US009162040B2

# (12) United States Patent
Vo et al.

(10) Patent No.: US 9,162,040 B2
(45) Date of Patent: Oct. 20, 2015

(54) **BALLOON CATHETER AND METHOD OF USE**

(71) Applicants: **Stryker Corporation**, Kalamazoo, MI (US); **Stryker NV Operations Limited**, Dublin (IE)

(72) Inventors: **Justin T. Vo**, San Jose, CA (US); **Jon Schabert**, Dublin, CA (US)

(73) Assignees: **STRYKER CORPORATION**, Kalamazoo, MI (US); **STRYKER EUROPEAN HOLDINGS I, LLC**, Kalamazoo, MI (US)

( * ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 277 days.

(21) Appl. No.: **13/722,948**

(22) Filed: **Dec. 20, 2012**

(65) **Prior Publication Data**

US 2013/0184644 A1 Jul. 18, 2013

**Related U.S. Application Data**

(63) Continuation-in-part of application No. 13/413,486, filed on Mar. 6, 2012, now Pat. No. 8,585,643.

(60) Provisional application No. 61/449,996, filed on Mar. 7, 2011.

(51) **Int. Cl.**

***A61M 31/00*** (2006.01)
***A61M 25/10*** (2013.01)

(Continued)

(52) **U.S. Cl.**

CPC ............. ***A61M 25/10*** (2013.01); ***A61M 25/005*** (2013.01); ***A61M 25/0053*** (2013.01);

(Continued)

(58) **Field of Classification Search**

CPC ..................... A61M 25/10; A61M 2025/0059; A61M 25/005; A61M 25/0053; A61M 25/0054; A61M 25/0138; A61M 2025/09133; A61M 25/0013; A61M 25/0043; A61M 25/0051; A61M 25/0144; A61M 2025/0681; A61M 2025/1063; A61M 25/0012; B26D 3/16; Y10T 29/49826; A61F 2/958

USPC .................................................... 604/103.09

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,106,455 A 4/1992 Jacobsen et al.
5,238,004 A 8/1993 Sahatjian et al.

(Continued)

FOREIGN PATENT DOCUMENTS

WO 2006135964 12/2006

OTHER PUBLICATIONS

PCT International Search Report and Written Opinion for PCT/US2012/027910, Applicant Stryker Corporation forms PC/ISA/210, 220, and 237, dated May 18, 2012 (15 pages).

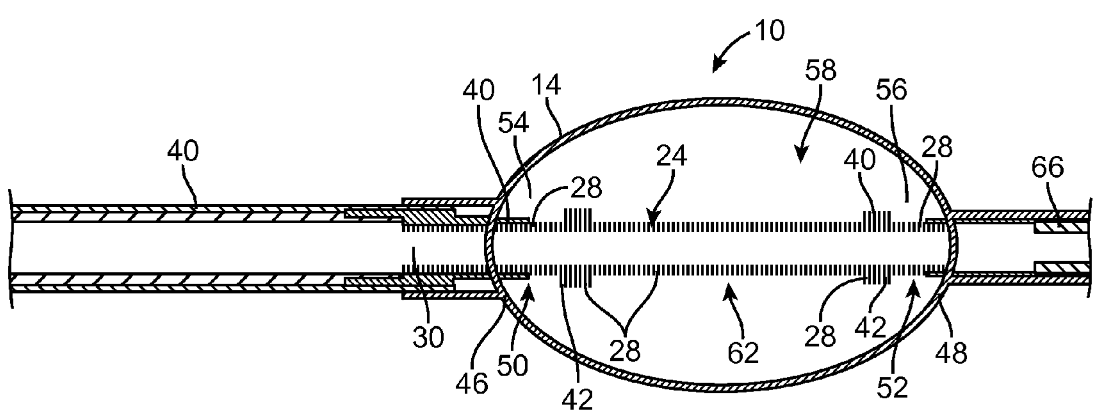
*Primary Examiner* — Jason Flick

(74) *Attorney, Agent, or Firm* — Vista IP Law Group LLP

(57) **ABSTRACT**

A balloon catheter includes an elongate support member defining first and second openings therein, open proximal and distal ends, and an axial lumen; and a balloon disposed on the elongate support member, the balloon defining a balloon interior through which the support member extends, where the balloon interior has a proximal end region, a middle region, and a distal end region, with the first opening located in the middle region, and the second opening located in the distal end region, such that the support member lumen is in communication with the balloon interior through each of the first and second openings, and such that a pressurized liquid introduced through the open proximal end of the support member will enter the balloon interior through the first opening, and subsequently exit the balloon interior through the second opening, back into the lumen, and out the open distal end of the support member.

**16 Claims, 15 Drawing Sheets**



(51) **Int. Cl.**
***A61M 25/00*** (2006.01)
***B26D 3/16*** (2006.01)

(52) **U.S. Cl.**
CPC ............ ***A61M 25/0054*** (2013.01); ***B26D 3/16*** (2013.01); *A61M 2025/0059* (2013.01); *Y10T 29/49826* (2015.01); *Y10T 83/0304* (2015.04)

(56) **References Cited**

U.S. PATENT DOCUMENTS

| | | | |
|---|---|---|---|
| 5,772,609 | A | 6/1998 | Nguyen et al. |
| 6,139,510 | A | 10/2000 | Palermo |
| 6,508,803 | B1 | 1/2003 | Horikawa et al. |
| 6,579,246 | B2 | 6/2003 | Jacobsen et al. |
| 6,766,720 | B1 | 7/2004 | Jacobsen et al. |
| 6,918,882 | B2 | 7/2005 | Skujins et al. |
| 7,071,197 | B2 | 7/2006 | Leonardi et al. |
| 7,878,984 | B2 | 2/2011 | Jacobsen et al. |
| 2002/0082585 | A1 | 6/2002 | Carroll et al. |
| 2003/0069522 | A1 | 4/2003 | Jacobsen et al. |
| 2004/0181174 | A2 | 9/2004 | Davis et al. |
| 2005/0197668 | A1* | 9/2005 | Lim et al. ...................... 606/194 |
| 2006/0122537 | A1 | 6/2006 | Reynolds et al. |
| 2007/0083132 | A1 | 4/2007 | Sharrow |
| 2007/0135763 | A1* | 6/2007 | Musbach et al. ........... 604/96.01 |
| 2009/0156999 | A1 | 6/2009 | Adams |

* cited by examiner

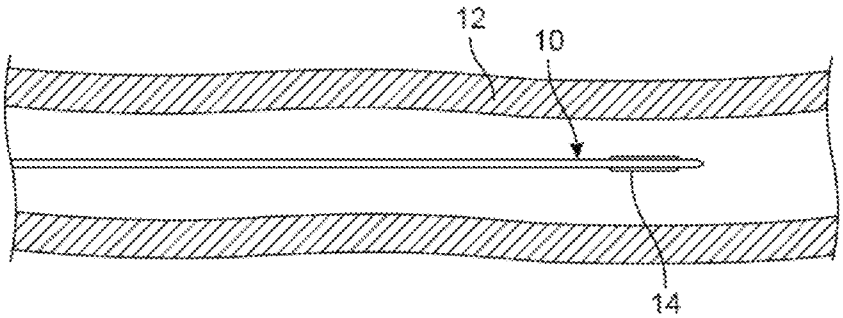



FIG. 1

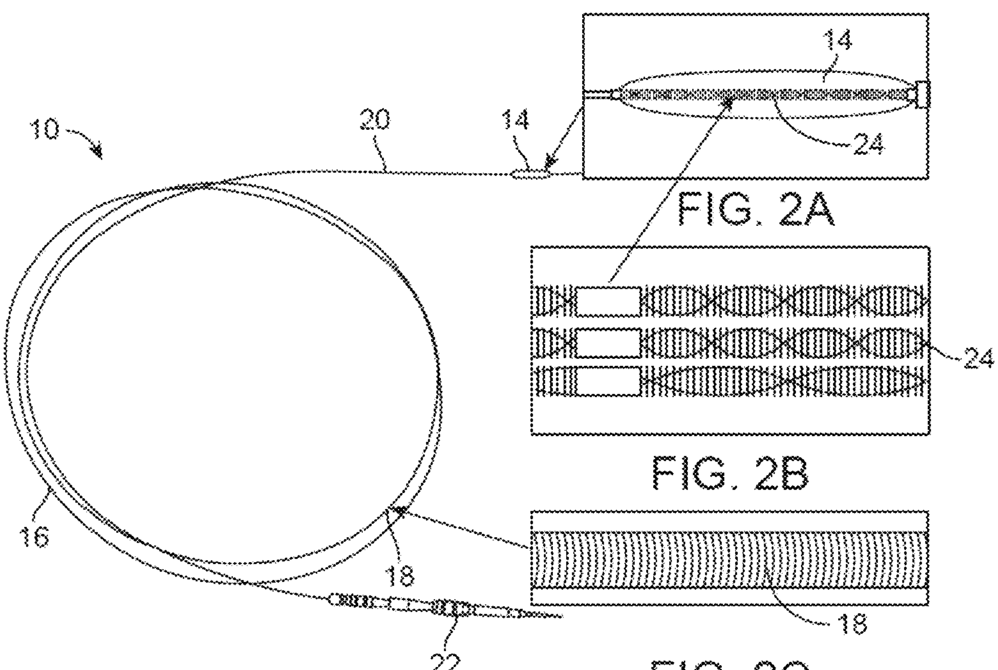



FIG. 2

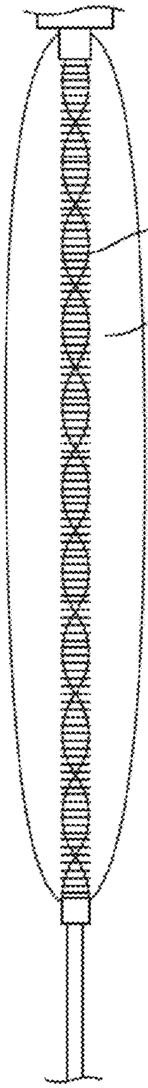



FIG. 3A

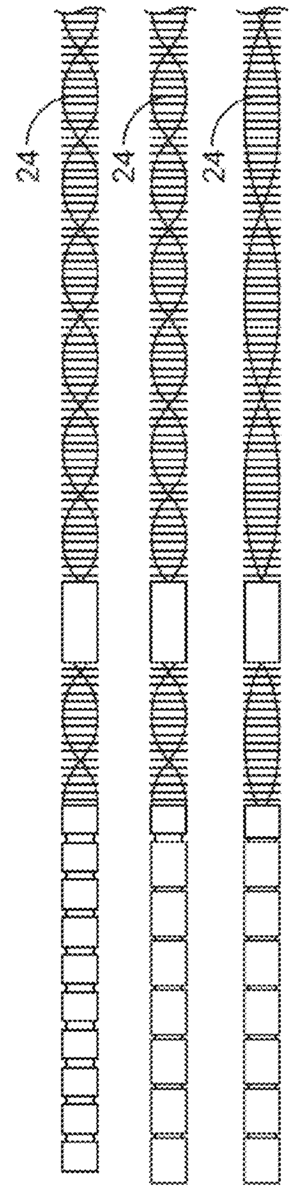



FIG. 3B

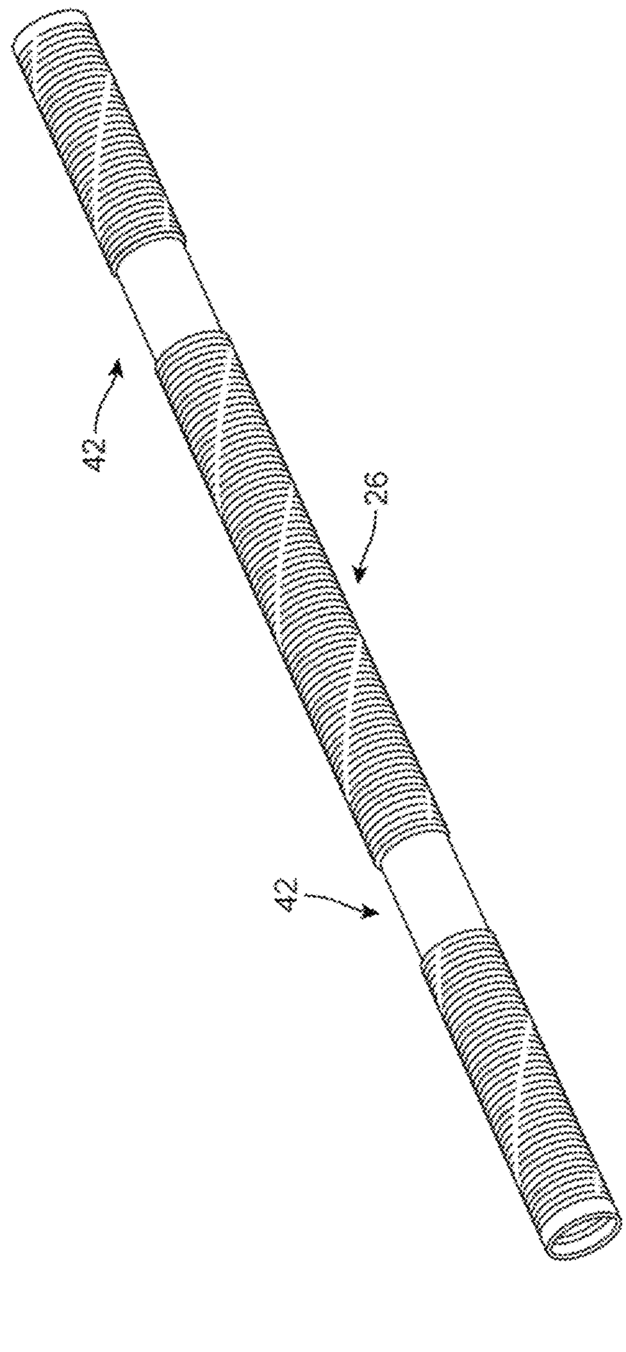



FIG. 4

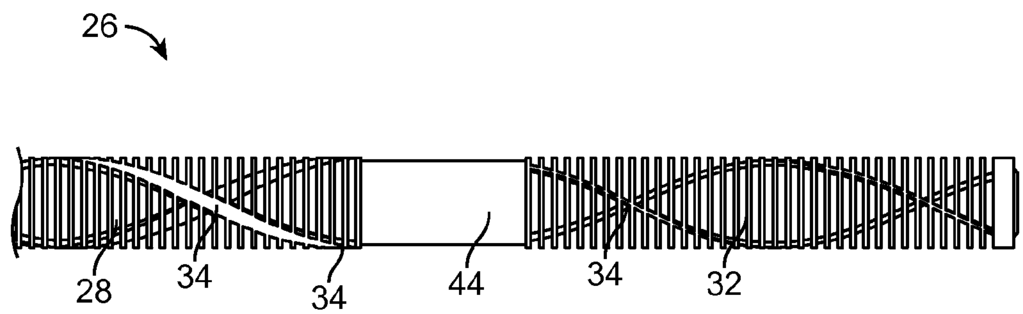



FIG. 5

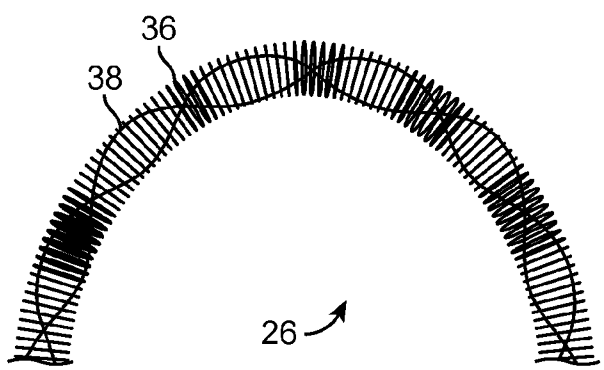



FIG. 6

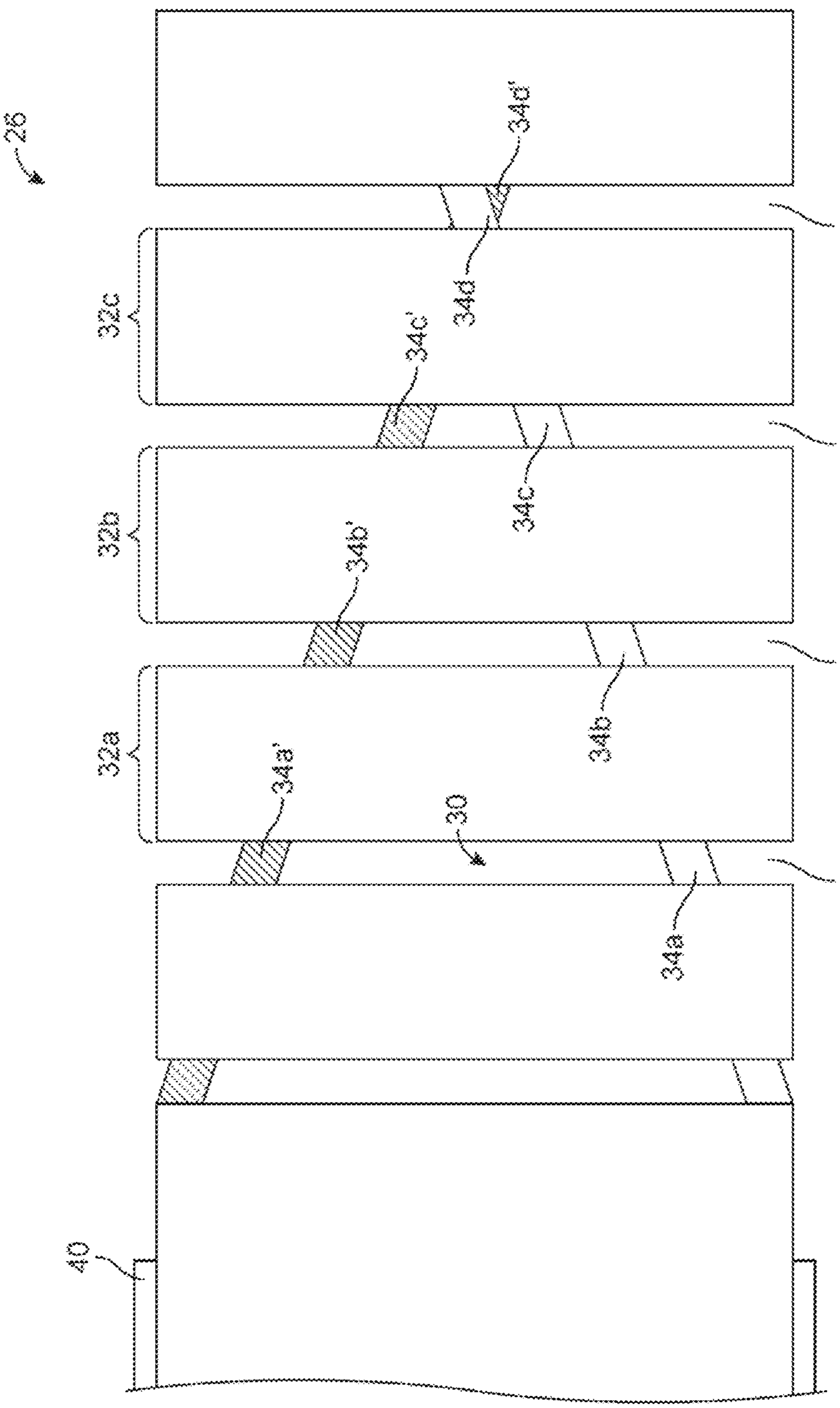

26
34d'
28d
32c
34d
34c'
28c
32b
34c
34b'
28b
32a
34b
34a'
30
28a
34a
40

FIG. 7

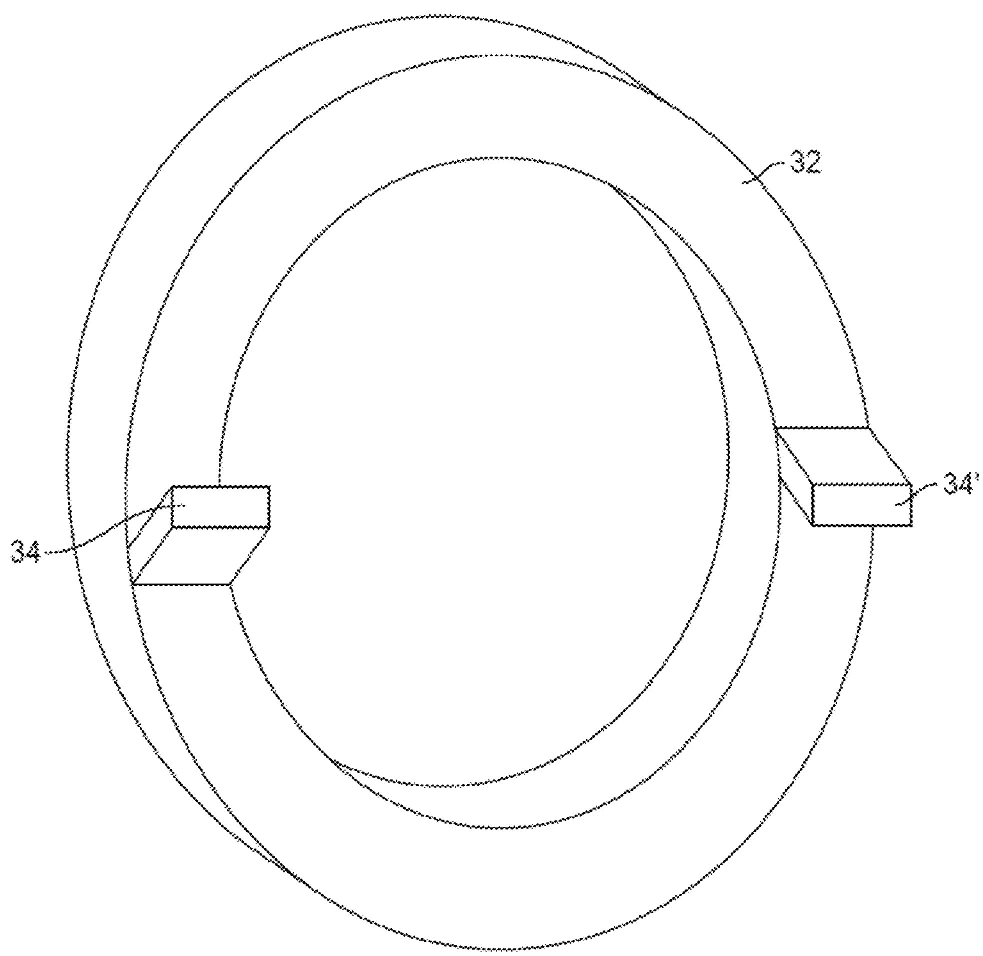



FIG. 8

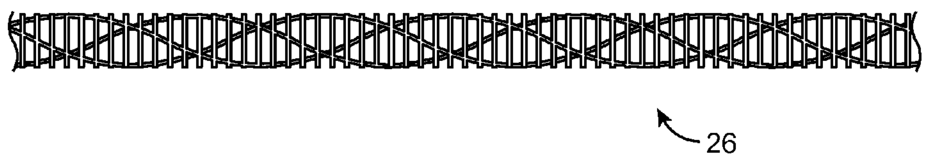



FIG. 9

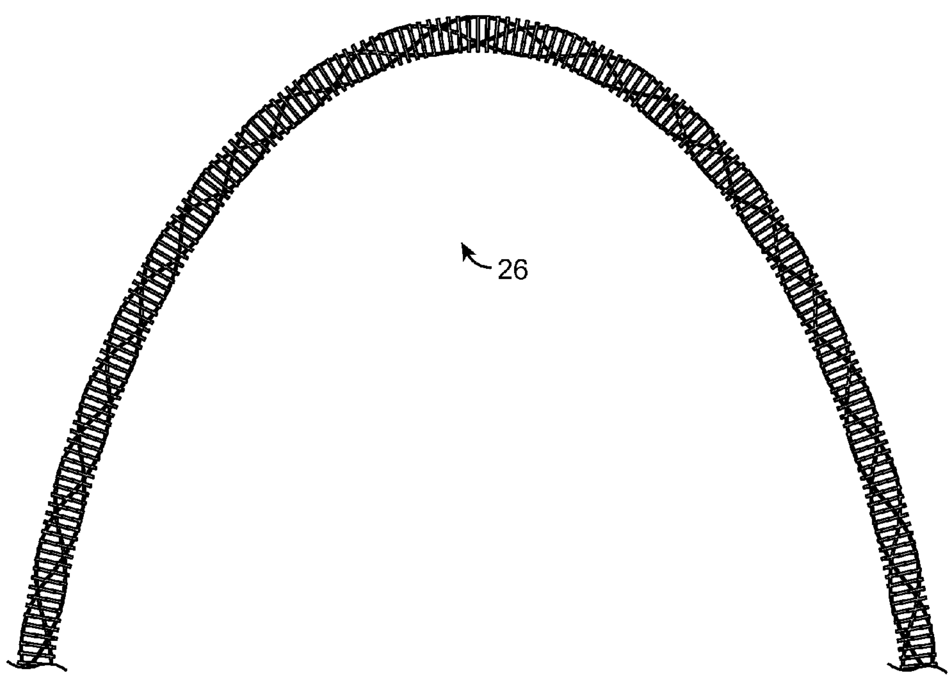



FIG. 10

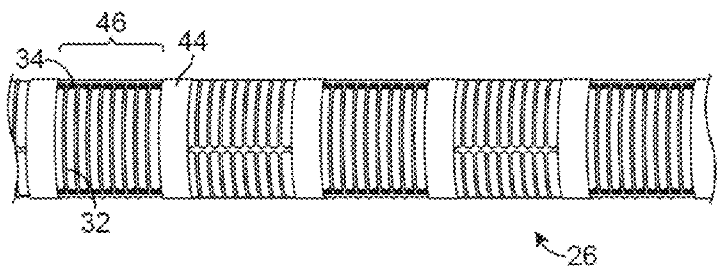



FIG. 11

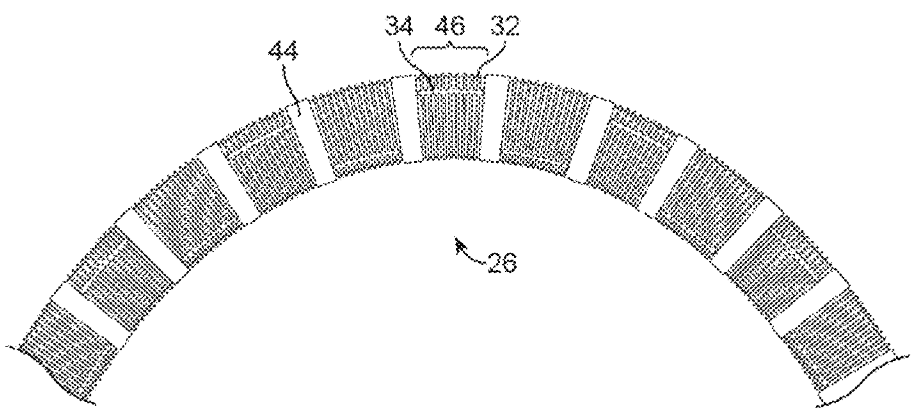



FIG. 12

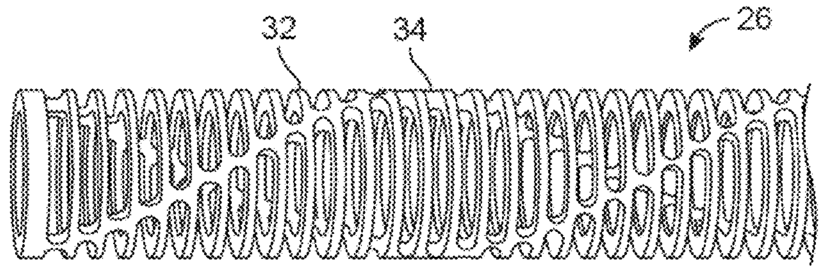



FIG. 13A

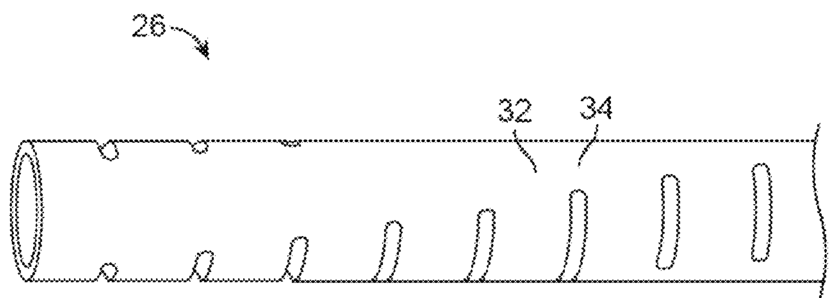



FIG. 13B

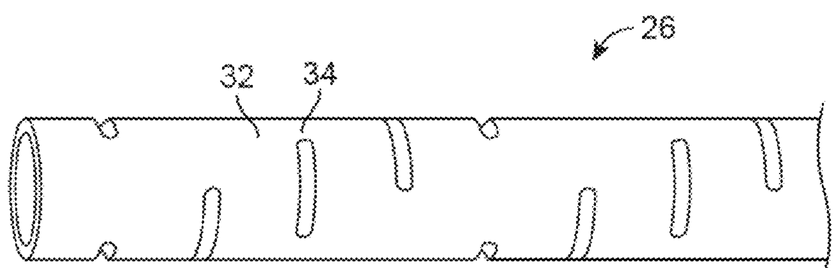



FIG. 13C

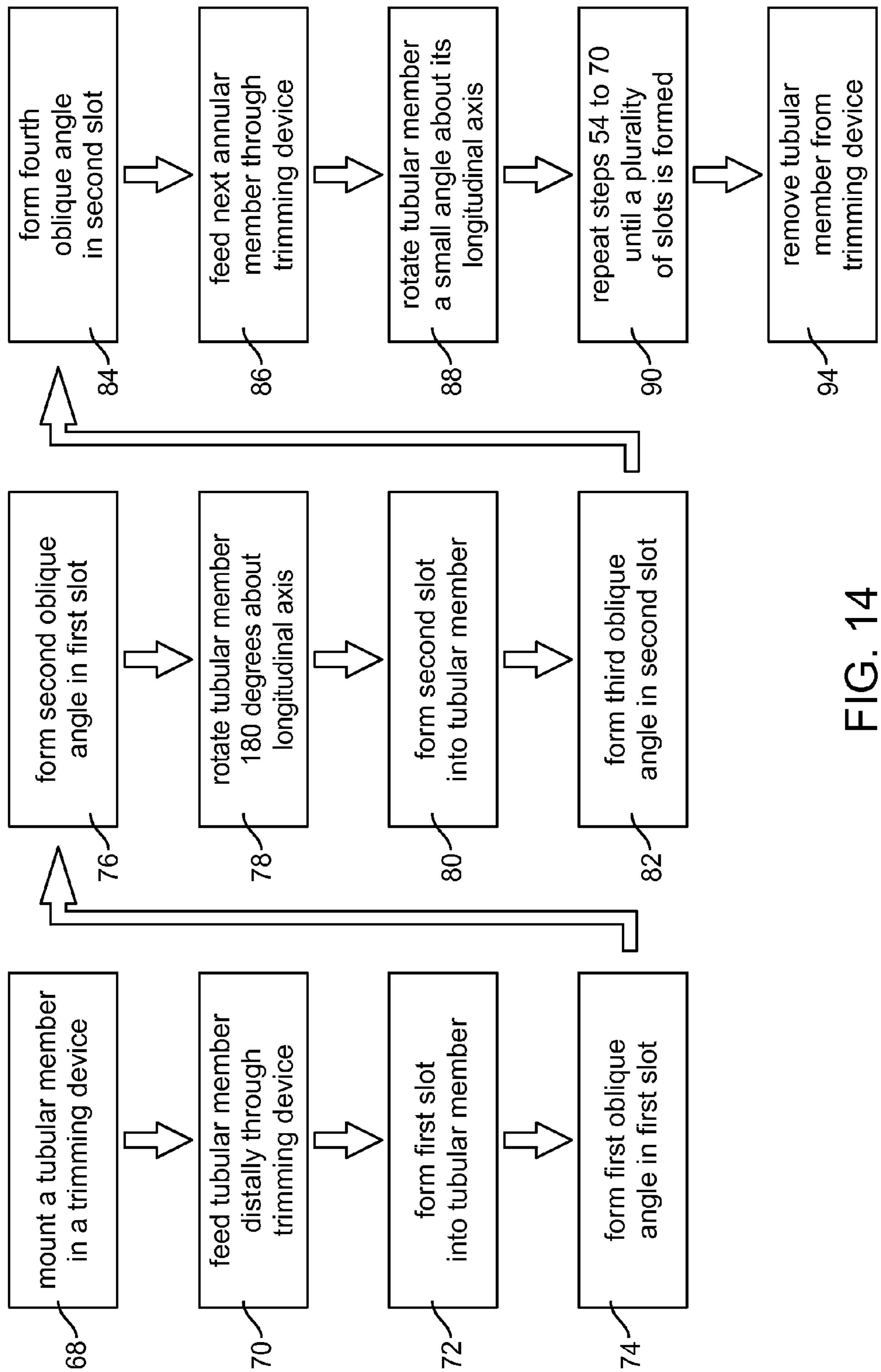

mount a tubular member in a trimming device
68
feed tubular member distally through trimming device
70
form first slot into tubular member
72
form first oblique angle in first slot
74
form second oblique angle in first slot
76
rotate tubular member 180 degrees about longitudinal axis
78
form second slot into tubular member
80
form third oblique angle in second slot
82
form fourth oblique angle in second slot
84
feed next annular member through trimming device
86
rotate tubular member a small angle about its longitudinal axis
88
repeat steps 54 to 70 until a plurality of slots is formed
90
remove tubular member from trimming device
94

FIG. 14

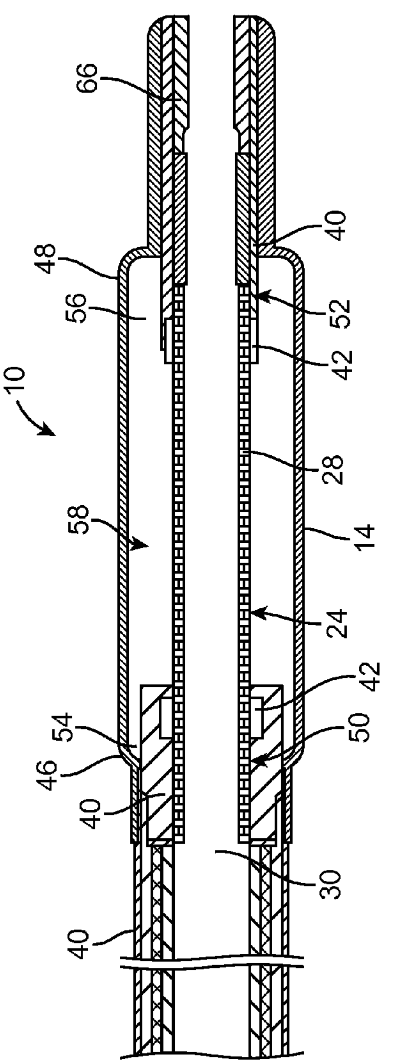

66
48
40
56
52
42
10
58
28
14
24
42
54
50
46
40
30
40

FIG. 15

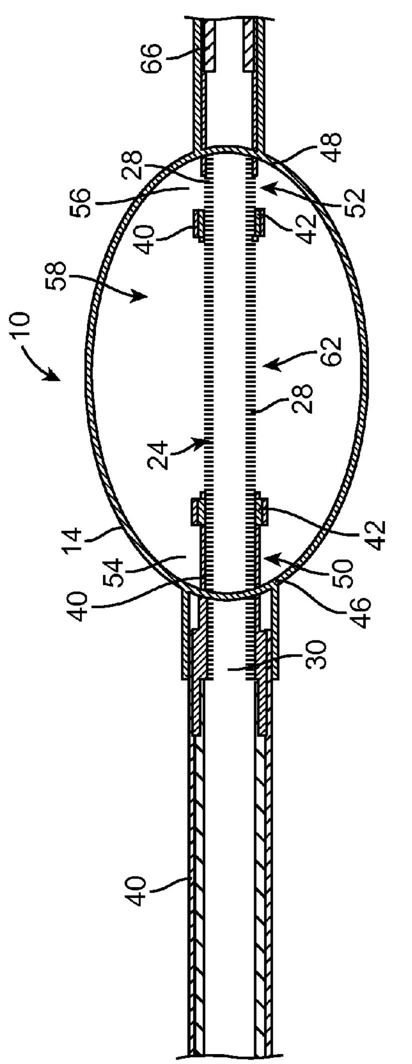

66
28
48
56
52
40
42
58
10
62
28
24
42
14
54
50
40
46
30
40

FIG. 16

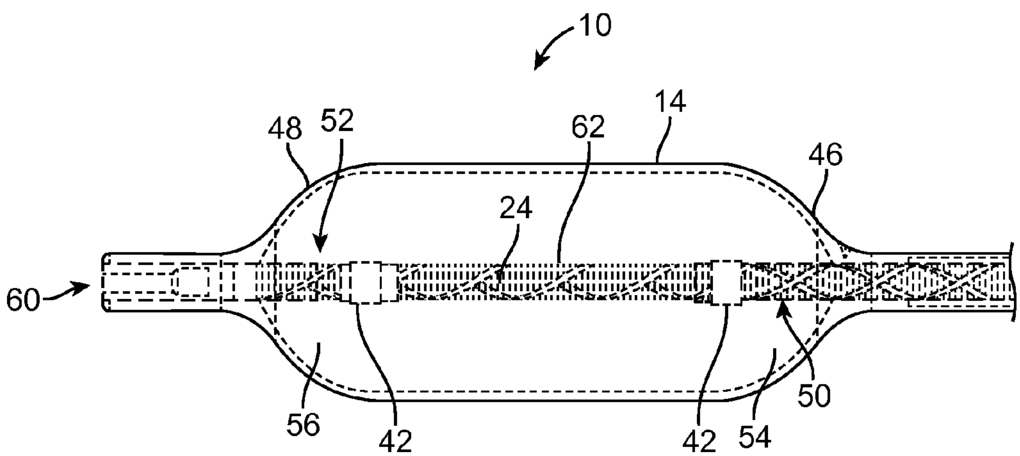



FIG. 17

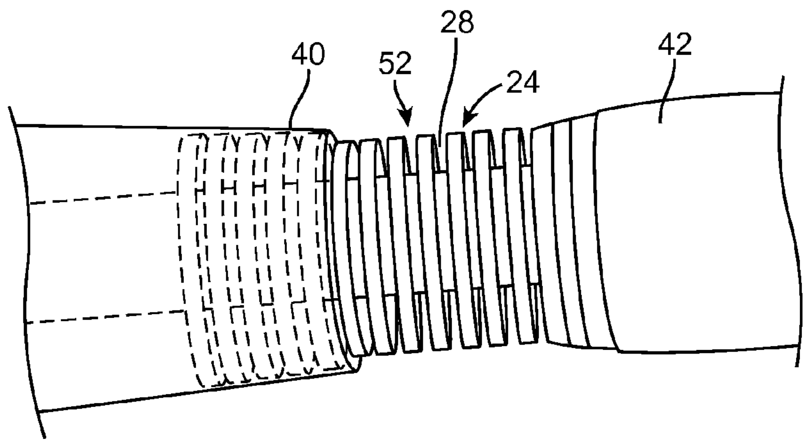



FIG. 18

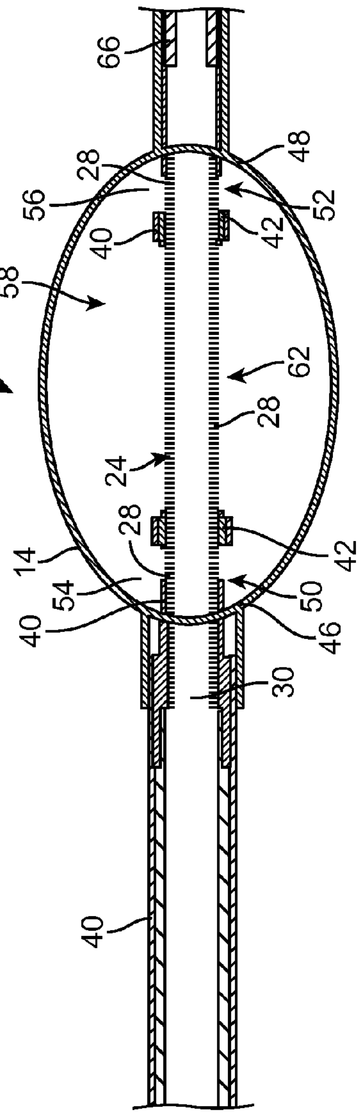

10
66
28
56
58
40
42
48
52
62
28
24
28
14
54
40
42
50
46
30
40

FIG. 19

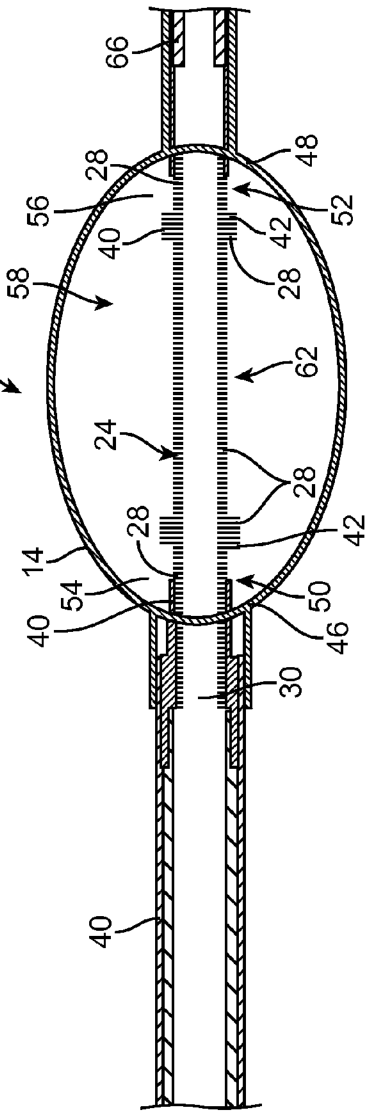

10
66
28
56
58
40
42
28
48
52
62
24
28
14
54
40
42
50
46
30
40

FIG. 20

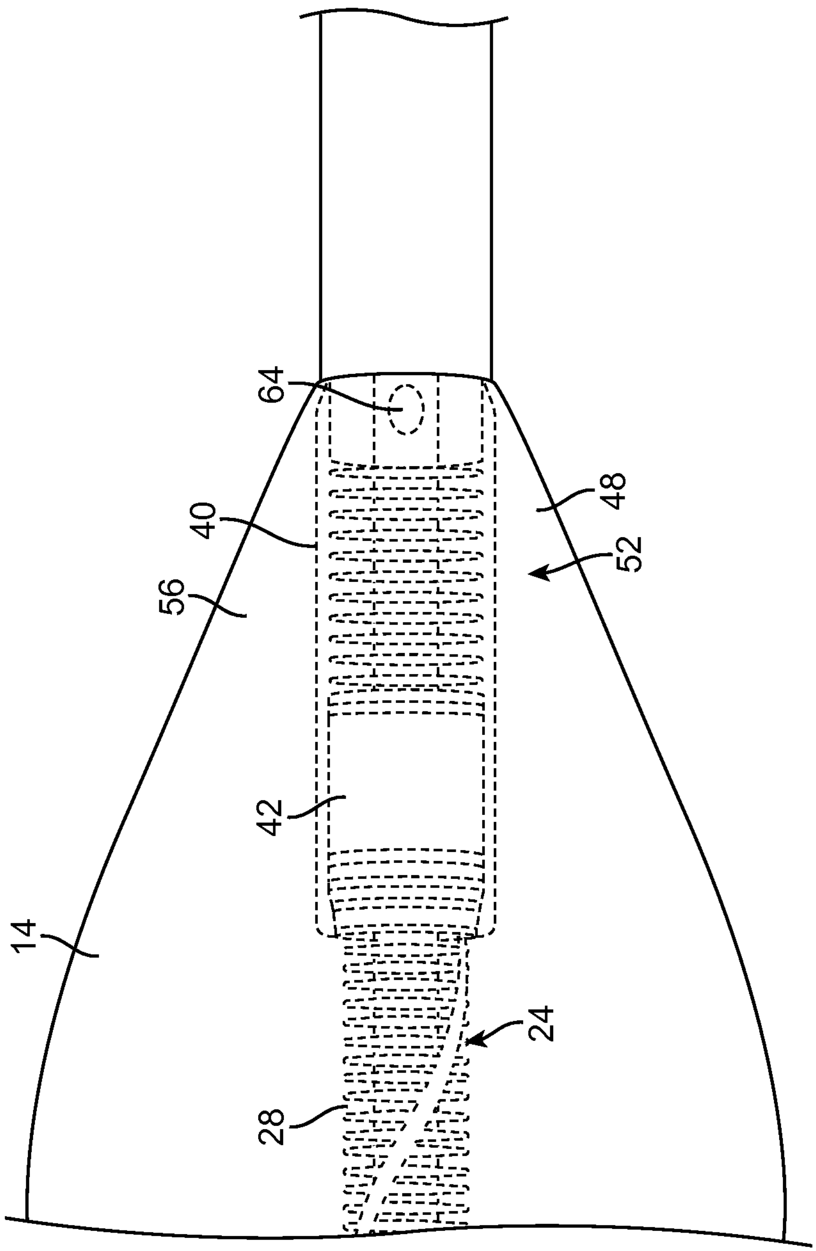



FIG. 21

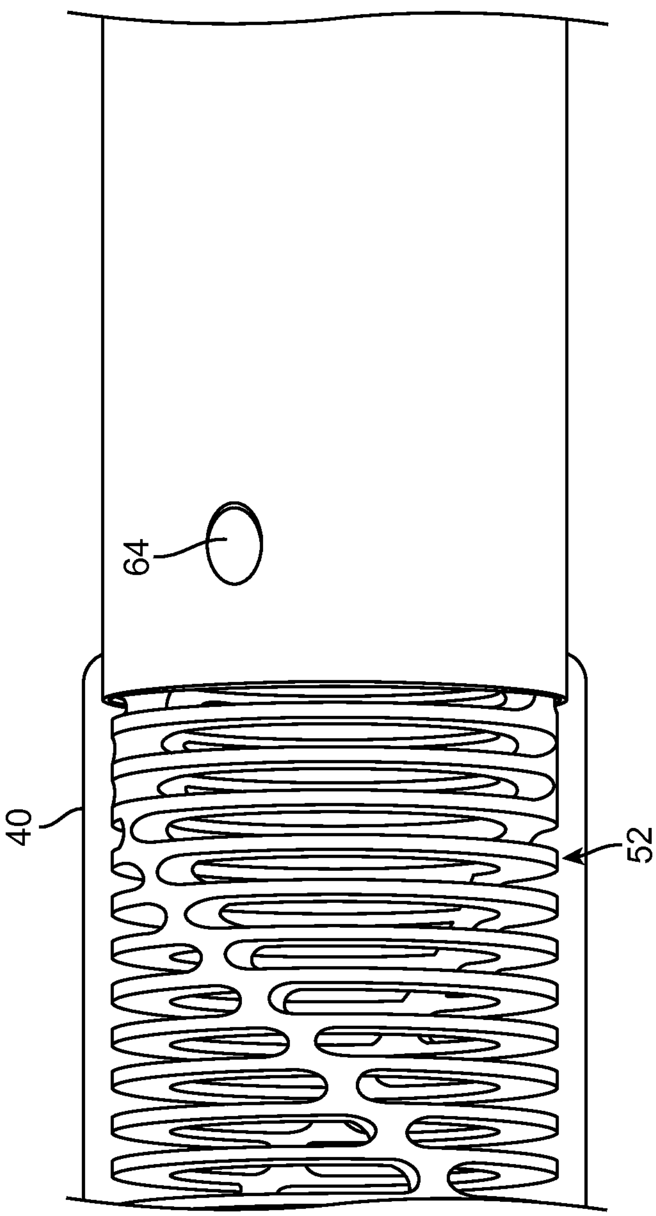



FIG. 22

# BALLOON CATHETER AND METHOD OF USE

## RELATED APPLICATION DATA

The present application is a continuation-in-part of application Ser. No. 13/413,486, filed Mar. 6, 2012, which claims the benefit under 35 U.S.C. §119 to U.S. Provisional Application No. 61/449,996, filed Mar. 7, 2011, the entire contents of both of which are incorporated herein by reference as though set forth in full.

## FIELD

The present disclosure relates generally to medical devices and methods of manufacturing such devices. More particularly, the present disclosure relates to balloon catheters and balloon catheter support shafts.

## BACKGROUND

The use of intravascular medical devices has become an effective method for treating many types of vascular disease. In general, a suitable intravascular device is inserted into the vascular system of the patient and navigated through the vasculature to a desired target site. Using this method, virtually any target site in the patient's vascular system may be accessed, including the coronary, cerebral, and peripheral vasculature.

Catheters are often utilized to place medical devices such as stents and embolic devices at a desired location within the body. A medical prosthesis, such as a stent for example, may be loaded onto a catheter in a configuration having a reduced diameter and then introduced into the lumen of a body vessel. Once delivered to a target location within the body, the stent may then be expanded to an enlarged configuration within the vessel to support and reinforce the vessel wall while maintaining the vessel in an open, unobstructed condition. The stent may be configured to be self-expanding, expanded by an internal radial force such as a balloon, or a combination of self-expanding and balloon expandable.

Balloon catheters are used in a number of endovascular applications including temporarily or permanently occluding blood flow either distal or proximal of a treatment site during neurological examinations, delivering diagnostic agents such as contrast media, assisting in neurovascular embolic coiling of an aneurysm or arteriovenous malformation (AVM), and dilating narrowed blood vessels caused by vasospasm. During therapeutic procedures such as the ones mentioned above, fast aspiration-mediated deflation of the balloon catheter quickly restores sufficient or normal blood flow to the brain in order to avoid potential neurological impairment, such as weakness, loss of sensation, speech problems, etc.

Current single lumen balloon catheters have a few inflation/deflation ports either punched or laser drilled in the polymeric elongated distal shaft. An inadequate seal between the balloon distal tip and the guidewire may lead to blood entering the balloon, which may result in poor balloon visibility and clot formation around the inflation/deflation ports. In an emergency involving a balloon catheter, a physician may be forced to "bail out" by withdrawing the guidewire proximally away from the balloon to instantly deflate the balloon to restore blood flow to the brain. Poor balloon visibility and inability to quickly deflate the balloon during a procedure could lead to vessel damage and other serious complications.

In preparation for use, balloon catheters are flushed with fluid, such as saline. This fluid can be introduced using a



syringe connected to a hub, such as a Luer fitting with a rotary selector valve. Air in these parts can be introduced as air bubbles into the balloon catheter during flushing. The difference between the outer diameter of the balloon support member and the inner diameter of the balloon results in the formation of an annular space and air bubble entrapment in the balloon catheter during flushing. Air bubble entrapment is especially problematic in larger diameter compliant and super compliant balloons.

Due to the pressure differential along the longitudinal axis of the balloon catheter, many air bubbles collect in the distal end of the balloon. However, with larger diameter balloons, air bubbles may also collect in the proximal end of the balloon. Collected air bubbles can be larger than 1 mm in diameter and may interfere with visualization of the balloon catheter. Further, air bubble may also dislodge from the balloon in vivo, resulting in air embolisms and strokes. Accordingly, after a balloon catheter is flushed during preparation, its balloon is inflated to a nominal diameter and visually inspected to identify any air bubbles above a certain size, e.g., 1 mm. If more than a predetermined number of such air bubbles are identified, the balloon catheter may be "re-prepped" by repeating the cycle of flushing, inflating, and inspecting. However, re-prepping the balloon catheter may expand the dead spaces in the balloon where air bubbles are entrapped, and the dead spaces may retain air bubbles after several cycles of prepping.

A number of different balloon catheters are known, each having certain advantages and disadvantages. However, there is an ongoing need to provide alternative balloon catheters, in particular, alternative balloon catheters that facilitate isotropic bending and rapid deflation, and methods of making such catheters. There is also an ongoing need to provide alternative balloon catheters with reduced air bubble formation during flushing.

## SUMMARY

In one embodiment of the disclosed inventions, a balloon catheter comprises an elongate support member comprising a tubular wall defining first and second openings therein, open proximal and distal ends, and an axial lumen in communication with the first and second openings and the open proximal and distal ends; and a balloon disposed on the elongate support member, the balloon defining a balloon interior through which the elongate support member extends, wherein the balloon interior has a proximal end region, a middle region, and a distal end region, with the first opening located in the middle region, and the second opening located in the distal end region, such that the support member lumen is in communication with the balloon interior through each of the first and second openings, and such that a pressurized liquid introduced through the open proximal end of the support member will enter the balloon interior through the first opening, and subsequently exit the balloon interior through the second opening, back into the lumen, and out the open distal end of the support member.

The second opening may be a slot defined by the elongate support member. The balloon catheter may also comprise a radiopaque marker disposed in the balloon interior on the elongate support member between the first opening and the second opening, the radiopaque marker comprising a marker tubular wall or an open pitch coil defining a marker opening therein, wherein the tubular wall of the elongate support member also defines a third opening therein at least partially underlying the marker opening, such that the support member lumen is in communication with the balloon interior through the third opening and the marker opening. The elongate support member may be a metal hypotube, and the first and second openings are micro-machined therein or a polymeric tube, and the first and second openings are drilled therein. The elongate support member may also comprise a polymeric sleeve disposed around a portion of the elongate support member, and wherein the portion of the elongate support member in which the second opening is formed is free of the polymeric sleeve. Alternatively or additionally, the elongate support member may also comprise an annular seal disposed in the lumen distal of the balloon.

In some embodiments of the disclosed inventions, the tubular wall also defines a third opening located in the proximal end region, such that the support member lumen is in communication with the balloon interior through the third opening, and such that a pressurized liquid introduced into the open proximal end of the support member will enter the balloon interior through the first opening, and subsequently exit the balloon interior through the second and third openings, back into the lumen, and out the open distal end of the support member. In such embodiments, the balloon comprises a compliant or super compliant material.

In another embodiment of the disclosed inventions, a balloon catheter comprises an elongate support member comprising a tubular wall defining first, second, and third slot-shaped openings therein, open proximal and distal ends, and an axial lumen in communication with the first, second, and third openings and the open proximal and distal ends; and a balloon disposed on the elongate support member, the balloon defining a balloon interior surrounding a portion of the elongate support member, wherein the balloon interior has a proximal end region, a middle region, and a distal end region, with the first opening located in the middle region, the second opening located in the distal end region, and the third opening located in the proximal end region, such that the support member lumen is in communication with the balloon interior through each of the first, second, and third openings, and such that a pressurized liquid introduced through the open proximal end of the support member will enter the balloon interior through the first opening, and subsequently exit the balloon interior through the second and third openings, back into the lumen, and out the open distal end of the support member.

The balloon catheter may also comprise a radiopaque marker disposed in the balloon interior on the elongate support member between the first opening and the second opening, the radiopaque marker comprising a marker tubular wall or an open pitch coil defining a marker opening therein, wherein the tubular wall of the elongate support member also defines a fourth opening therein at least partially underlying the marker opening, such that the support member lumen is in communication with the balloon interior through the fourth opening and the marker opening. The elongate support member may also comprise a polymeric sleeve disposed around a portion of the elongate support member, and wherein the portions of the elongate support member in which the second and third openings are formed are free of the polymeric sleeve. Alternatively or additionally, the elongate support member may also comprise an annular seal disposed in the lumen distal of the balloon. The balloon may comprise a compliant or super compliant material.

In yet another embodiment of the disclosed inventions, a method of flushing a balloon catheter while minimizing bubble formation, the balloon catheter having a balloon disposed on an elongate support member having a tubular wall, the tubular wall defining first and second openings therein, open proximal and distal ends, and an axial lumen in communication with the first and second openings and the open proximal and distal ends, and the balloon defining a balloon interior through which the elongate balloon extends, wherein the balloon interior has a middle region and a distal end region, with the first opening located in the middle region, and the second opening located in the distal end region, the method comprises the following: (a) introducing a flushing liquid into the lumen through the open proximal end of the support member; and (b) applying a pressure to the flushing liquid such that the flushing liquid will enter the balloon interior through the first opening, and subsequently exit the balloon interior through the second opening, back into the lumen, and out the open distal end of the support member, and such that the flushing liquid will remove at least one air bubble from the balloon interior as the flushing liquid exits the balloon interior.

The method may also comprise the following: (c) inserting a guidewire into the lumen to form a substantially fluid-tight seal with the support member distal of the first and second openings; (d) introducing an inflation liquid into the lumen to at least partially inflate the balloon; and (e) inspecting the inflated balloon to identify air bubbles therein. The method may further comprise the following: (f) removing the guidewire from the lumen to break the substantially fluid-tight seal; (g) allowing the balloon to deflate; and (h) repeating steps (a) to (g) until less than a predetermined minimum number of air bubbles are identified in step (e).

Other and further aspects and features of embodiments of the disclosed inventions will become apparent from the ensuing detailed description in view of the accompanying figures.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a plan view of a balloon catheter constructed according to one embodiment of the disclosed inventions and disposed in a vessel.

FIG. **2** is a perspective view of a balloon catheter constructed according to one embodiment of the disclosed inventions, including insets showing the catheter shaft, the balloon and various balloon support shafts.

FIG. **2**A is a detailed perspective view of the balloon and balloon support shaft of the balloon catheter depicted in FIG. **2**.

FIG. **2**B is a detailed perspective view of the balloon support shafts according to various embodiments of the invention.

FIG. **2**C is a detailed perspective view of the reinforced catheter shaft of the balloon catheter depicted in FIG. **2**.

FIG. **3**A is a detailed perspective view of a balloon catheter according to one embodiments of the disclosed inventions.

FIG. **3**B is a detailed perspective view of various balloon support shafts according to various embodiments of the disclosed inventions.

FIG. **4** is a perspective view of a balloon support shaft constructed according to one embodiment of the disclosed inventions.

FIG. **5** is a perspective view of a balloon support shaft constructed according to one embodiment of the disclosed inventions.

FIG. **6** is a perspective view of the balloon support shaft of FIG. **5** in a bent configuration.

FIG. **7** is a detailed side view of a balloon support shaft constructed according to one embodiment of the disclosed inventions.

FIG. **8** is a detailed end view of an annular segment and two beams of a balloon support shaft constructed according to one embodiment of the disclosed inventions.

FIG. **9** is a perspective view of a balloon support shaft constructed according to one embodiment of the disclosed inventions.

FIG. **10** is a perspective view of the balloon support shaft of FIG. **9** in a bent configuration.

FIG. **11** is a perspective view of a balloon support shaft constructed according to one embodiment of the disclosed inventions.

FIG. **12** is a perspective view of the balloon support shaft of FIG. **11** in a bent configuration.

FIGS. **13**A-C are detailed perspective views of balloon support shafts according to various embodiments of the disclosed inventions.

FIG. **14** is a flow chart showing a method of manufacturing a balloon support shaft according to one embodiment of the disclosed inventions.

FIG. **15** is a detailed longitudinal cross-sectional view of the distal portion of a balloon catheter according to one embodiment of the disclosed inventions.

FIG. **16** is a detailed longitudinal cross-sectional view of the distal portion of a balloon catheter according to another embodiment of the disclosed inventions.

FIG. **17** is a detailed side schematic view of the distal portion of a balloon catheter according to yet another embodiment of the disclosed inventions, with the balloon shown as transparent to depict the elements contained therein.

FIG. **18** is a detailed side schematic view of the distal portion of a balloon catheter according to yet another embodiment of the disclosed inventions.

FIGS. **19** and **20** are detailed longitudinal cross-sectional views of the distal portions of two balloon catheters according to two different embodiments of the disclosed inventions.

FIGS. **21** and **22** are detailed side schematic views of the distal portion of a balloon catheter according to yet another embodiment of the disclosed inventions.

## DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

For the following defined terms, these definitions shall be applied, unless a different definition is given in the claims or elsewhere in this specification.

All numeric values are herein assumed to be modified by the term "about," whether or not explicitly indicated. The term "about" generally refers to a range of numbers that one of skill in the art would consider equivalent to the recited value (i.e., having the same function or result). In many instances, the terms "about" may include numbers that are rounded to the nearest significant figure.

The recitation of numerical ranges by endpoints includes all numbers within that range (e.g., 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).

As used in this specification and the appended claims, the singular forms "a", "an", and "the" include plural referents unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term "or" is generally employed in its sense including "and/or" unless the content clearly dictates otherwise.

Various embodiments of the disclosed inventions are described hereinafter with reference to the figures. The figures are not necessarily drawn to scale, the relative scale of select elements may have been exaggerated for clarity, and elements of similar structures or functions are represented by like reference numerals throughout the figures. It should also be understood that the figures are only intended to facilitate the description of the embodiments, and are not intended as an exhaustive description of the invention or as a limitation on the scope of the invention, which is defined only by the appended claims and their equivalents. In addition, an illustrated embodiment of the disclosed inventions needs not have all the aspects or advantages shown. An aspect or an advantage described in conjunction with a particular embodiment of the disclosed inventions is not necessarily limited to that embodiment and can be practiced in any other embodiments even if not so illustrated.



FIG. **1** is a plan view of a balloon catheter **10** disposed in a blood vessel **12**. Balloon catheter **10** includes a balloon **14** configured to expand to seal vessels **12** within the anatomy of a patient. Balloon catheter **10** may be used for intravascular procedures. For example, balloon catheter **10** may be used in conjunction with other medical devices, such as a stent or a vaso-occlusive device, to treat and/or diagnose a medical condition.

FIG. **2** shows a balloon catheter **10** including an elongate member **16** having a proximal portion **18** and a distal portion **20**. In FIG. **2**, much of the proximal portion **18** is wound into a loop to display the entire catheter shaft design. An inflation source **22**, such as a 1 cc or 3 cc syringe **22**, is attached to the elongate member **16** at its proximal end using a three-way stopcock. A balloon **14** is attached to the distal end of the elongate member **16**. The balloon **14** is also shown in an inset (**2***a*) in sufficient detail to display the balloon support shaft **24** in the distal portion **20** of the elongate member **16**. A second inset (**2***b*) shows several balloon support shafts **24** according to various embodiments of the inventions. A third inset (**2***c*) shows a reinforced catheter shaft in the proximal portion **18** of the elongate member **16**.

FIGS. **3**A-**8** show various features of the balloon support shaft **24** according to one embodiment of the inventions that will be discussed in greater detail below. As shown in FIGS. **3**B, **4**, **5**, and **7**, the balloon support shaft **24** has a tubular member **26** with slots **28** formed therein. When supporting a balloon **14** in a balloon catheter **10**, as shown in FIG. **3**A, at least a part of the tubular member **26** is disposed inside the balloon **14**. The tubular member **26** defines a lumen **30** that accommodates a guidewire (not shown) and provides a fluid path for inflation and deflation of the balloon **14**. The structure of the tubular member **26** allows fluid communication between the lumen **30** the balloon **14** through the slots **28**. A guidewire seal is provided at the distal end of the balloon **14** to provide a fluid seal about the guidewire. The inflation source **22** is fluidly connected to the lumen **30** into which it can introduce and withdraw inflation fluid and contrast medium. From the proximal opening of the lumen **30**, the introduced fluid travels around the guidewire disposed in the lumen **30**, through the slots **28**, and into the interior of the balloon **14** to facilitate inflation and deflation thereof.

FIG. **7** shows the detailed structure of a tubular member **26** according to one embodiment of the inventions. The tubular member **26** is generally a stack of annular segments **32**. Tubular member **26** includes a plurality of slots **28** formed therein. Various embodiments of arrangements and configurations of slots **28** are contemplated. In some embodiments, at least some, if not all of slots **28** are disposed at the same or a similar angle with respect to the longitudinal axis of tubular member **26**. As shown, slots **28** can be disposed at an angle that is perpendicular, or substantially perpendicular, and/or can be characterized as being disposed in a plane that is normal to the longitudinal axis of tubular member **26**. However, in other embodiments, slots **28** can be disposed at an angle that is not perpendicular, and/or can be characterized as being disposed in a plane that is not normal to the longitudinal axis of tubular member **26**. Additionally, a group of one or more slots **28** may be disposed at different angles relative to another group of one or more slots **28**. The distribution and/or configuration of slots **30** can also include, to the extent applicable, any of those disclosed in U.S. Pat. No. 7,878,984, the entire disclosure of which is herein incorporated by reference.

Slots **28** enhance the flexibility of tubular member **26** while retaining suitable torque transmission characteristics. Slots **28** are formed such that the annular segments **32** are interconnected by one or more beams **34**, i.e., the portion of tubular member **26** remaining after slots **28** are formed therein. Such an interconnected structure displays a relatively high degree of torsional stiffness, while retaining a desired level of lateral flexibility. In some embodiments, some adjacent slots **28** can be formed such that they include portions that overlap with each other about the circumference of tubular member **26**. In other embodiments, some adjacent slots **28** can be disposed such that they do not necessarily overlap with each other, but are disposed in a pattern that provides the desired degree of lateral flexibility.

Additionally, slots **28** can be arranged along the length of, or about the circumference of, tubular member **26** to achieve desired properties. For example, adjacent slots **28**, or groups of slots **28**, can be arranged in a symmetrical pattern, such as being disposed essentially equally on opposite sides about the circumference of tubular member **26**, or can be rotated by an angle relative to each other about the axis of tubular member **26**. Additionally, adjacent slots **28**, or groups of slots **28**, may be equally spaced along the length of tubular member **26**, or can be arranged in an increasing or decreasing density pattern, or can be arranged in a non-symmetric or irregular pattern. Other characteristics, such as slot size, slot shape and/or slot angle with respect to the longitudinal axis of tubular member **26**, can also be varied along the length of tubular member **26** in order to vary the flexibility or other properties. In other embodiments, moreover, it is contemplated that the portions of the tubular member may not include any such slots **28**.

As suggested above, slots **28** may be formed in groups of two, three, four, five, or more slots **28**, which may be located at substantially the same location along the axis of tubular member **26**. Alternatively, a single slot **28** may be disposed at some or all of these locations. Within the groups of slots **28**, there may be included slots **28** that are equal in size (i.e., span the same circumferential distance around tubular member **26**). In some of these as well as other embodiments, at least some slots **28** in a group are unequal in size (i.e., span a different circumferential distance around tubular member **26**). Longitudinally adjacent groups of slots **28** may have the same or different configurations.

For example, some embodiments of tubular member **26** include slots **28** that are equal in size in a first group and then unequally sized in an adjacent group. It can be appreciated that in groups that have two slots **28** that are equal in size and are symmetrically disposed around the tube circumference, the centroid of the pair of beams **34** is coincident with the central axis of tubular member **26**. Conversely, in groups that have two slots **28** that are unequal in size and whose beams **34** are directly opposed on the tube circumference, the centroid of the pair of beams **34** is offset from the central axis of tubular member **26**. Some embodiments of tubular member **26** include only slot groups with centroids that are coincident with the central axis of the tubular member **26**, only slot groups with centroids that are offset from the central axis of tubular member **26**, or slot groups with centroids that are coincident with the central axis of tubular member **26** in a first group and offset from the central axis of tubular member **26** in another group. The amount of offset may vary depending on the depth (or length) of slots **28** and can include essentially any suitable distance.

Slots **28** can be formed by methods such as micro-machining, saw-cutting (e.g., using a diamond grit embedded semiconductor dicing blade), electron discharge machining, grinding, milling, casting, molding, chemically etching or treating, or other known methods, and the like. In some such embodiments, the structure of the tubular member **26** is formed by cutting and/or removing portions of the tube to form slots **28**. Some example embodiments of appropriate micromachining methods and other cutting methods, and structures for tubular members including slots and medical devices including tubular members are disclosed in U.S. Pat. Publication Nos. 2003/0069522 and 2004/0181174-A2; and U.S. Pat. Nos. 6,766,720; and 6,579,246, the entire disclosures of which are herein incorporated by reference. Some example embodiments of etching processes are described in U.S. Pat. No. 5,106,455, the entire disclosure of which is herein incorporated by reference. It should be noted that the methods for manufacturing balloon catheter **10** may include forming slots **28** in tubular member **26** using any of these or other manufacturing steps.

In at least some embodiments, slots **28** may be formed in tubular member using a laser cutting process. The laser cutting process may include essentially any suitable laser and/or laser cutting apparatus. For example, the laser cutting process may utilize a fiber laser. Utilizing processes like laser cutting may be desirable for a number of reasons. For example, laser cutting processes may allow tubular member **26** to be cut into a number of different cutting patterns in a precisely controlled manner. This may include variations in the slot width (which also may be termed "kerf"), annular segment width, beam height and/or width, etc. Furthermore, changes to the cutting pattern can be made without the need to replace the cutting instrument (e.g., a blade). This may also allow smaller tubes (e.g., having a smaller outer diameter) to be used to form tubular member **26** without being limited by a minimum cutting blade size. Consequently, tubular members **20** may be fabricated for use in neurological devices or other devices where a small size may be desired.

Because of the precision and control that may be achieved by cutting slots **28** with a laser, numerous additional variation can be achieved in slot **28** configurations, arrangements, etc. Still referring to FIG. **7**, a side view of tubular member **26** is illustrated. Tubular member **26** includes a plurality of annular segments **32** including annular segment **32***a*, annular segment **32***b*, and annular segment **32***c*. In this example, segment **32***a* is disposed longitudinally-adjacent (i.e., right next to) segment **32***b* and segment **32***c* is disposed longitudinally-adjacent segment **32***b* (oppositely segment **32***a*). The number of annular segments **32** in a given tubular member **26** may vary depending on the structure of tubular member **26**. For example, as the number of slots **28** increases, the number of annular segments **32** may similarly increase. The invention is not intended to be limited to any particular number or arrangement of annular segments **32** for any given tubular member **26** or device including a tubular member **26**.

Segments **32***a*/**32***b*/**32***c* can be understood to be generally circumferential or "round" portions of tubular member **26** that are defined between groups or sets of slots **28**. For example, segment **32***a* is defined between a first group of slots **28***a* and a second group of slots **28***b*. Likewise, segment **32***b* is defined between group **28***b* and a third group of slots **28***c*. Moreover, segment **32***c* is defined between group **28***c* and a fourth group of slots **28***d*. In this example, each group **28***a*/**28***b*/**28***c*/**28***d* includes two slots **28**. However, any suitable number of slots **28** may be utilized for any group **28**$a$/**28**$b$/**28**$c$/**28**$d$. Just like the annular segments **32**, the invention is not intended to be limited to any number of slots **28**, groups of slots **28**, or number of slots **28** per group for any given tubular member **26** or device including a tubular member **26** with slots **28**.

When slots **28** are formed in tubular member **26**, a portion of tubular member **26** remains at the longitudinal location where slots **28** are formed and extends between longitudinally-adjacent annular segments **32**. This portion is called a "beam" **34**. Several beams **34** are illustrated in FIG. **7** including beam **34***a*, beam **34***a*', beam **34***b*, beam **34***b*', beam **34***c*, beam **34***c*', beam **34***d*, and beam **34***d*'. Beams **34***a*/**34***a*'/**34***b*/**34***b*'/**34***c*/**34***c*'/**34***d*/**34***d*' can be understood to be portions of tubular member **26** that connects or attaches longitudinally-adjacent annular segments **32**. Each pair of longitudinally-adjacent annular segments (e.g., **32***a* and **32***b*) is attached by two beams (e.g., **34***b* and **34***b*'), which form a beam pair at the same longitudinal location along tubular member **26**. Similarly, segment **32***b* is attached to segment **32***c* by beams **34***c* and **34***c*'. In this example, each group **28***a*/**28***b*/**28***c*/**28***d* of slots **28** defines or leaves behind two, corresponding beams at a given longitudinal location. In FIG. **7**, which illustrates tubular member **26** from the side, one beam (e.g., **34***a*, **34***b*, **34***c*, **34***d*) of each beam pair can be seen from the front and the other beam (e.g., **34***a*', **34***b*', **34***c*', **34***d*') of the beam pair can be seen from the back and is shaded for clarity.

The beams **34**, **34**' are formed in the tubular member **26** such that they meet the annular segments **32** at an oblique angle, as shown in FIG. **8**. Further, each beam pair is formed in the tubular member **26** such that it is rotated about the longitudinal axis of the tubular member **26** from the previous beam pair. In this embodiment, each beam pair is angularly displaced or rotated by about eight degrees from the previous beam pair, resulting in a full rotation about every 45 beam pairs. The beam pairs form a double helix structure along the length of the tubular member **26** because of the oblique angle between beams **34** and annular segments **32**, and the angular displacement between beam pairs. These helices, which rotate in the same direction, are shown in FIGS. **2**, **3**, **5**, and **6**.

As the angle of rotation between adjacent beams **34** is reduced, the portion of the annular segment **32** between beams **34** shortens until it is non-existent on one side and completely isolated from loading (bending, tension and compression) on the other side. In embodiments having small angles of rotation, such as the one depicted in FIG. **5**, the beams **34** for a continuous helix. When such a structure is placed in compression or tension the helical line of beam pairs act as a continuous pair of fibers that effectively prevent length change of the structure. When loaded in tension the fibers are prevented from collapsing inward and straightening by the rib support of the annular segments **32**. Conversely, when loaded in compression, the fibers are prevented from buckling individually outward by the annular segments **32**.

As shown in FIG. **6**, the double helix arrangement of beams **34** causes the tubular member **26** to bend in a segmented manner, with more bending occurring in the first region **36** where the beam pair in the helix defines an axis approximately parallel to the plane of bending. Almost no bending in the second region **38** where the beam pair axis is perpendicular to the plane of bending. Increasing the pitch of the helices increases the likelihood that several bending regions **36** will exist in the tightest predicted radius of curvature of the balloon catheter **10**. As the angle of rotation between adjacent pairs of beams is increased the helix angle becomes tighter and the tubular member **26** may begin to twist into a ring when bent. The helix angle may be optimized to maximize both axial stiffness and isotropic properties in bending.

Increasing the number of beams **34** connecting each pair of annular segments **32** results in a tubular member **26** with more isotropic bending. Increasing the number connecting beams **34** from two to three gives the structure a more frequently repeating symmetry along its length. For example, a two beam structure (FIGS. **2**, **3**, **5**, and **6**) is symmetric at every 180 degrees of rotation while a three beam structure (FIGS. **9** and **10**) is symmetric at every 120 degrees of rotation. The three beam structure will not be as soft as a two beam structure, and may be more useful in proximal regions of the balloon catheter where greater stiffness is desired.

Forming groups **46** of beams **34** and narrow annular segments **32** that are rotated a large increment, such as 90 degrees, from each other where the groups **46** are joined by wider annular segments **44** also results in a more isotropic tubular structure **26**. The wider annular segments **44** are wide enough to resist stretching. FIGS. **11** and **12** show one example of such a structure. The beams **34** in each group **46** are all aligned in this example, however they could have a spiral pattern as well.

Just like slot groups **28***a*/**28***b*/**28***c*, the invention is not intended to be limited to any number of beams **34**, groups of beams **34**, or number of beams **34** per group for any given tubular member **26** or device including a tubular member **26** with beams **34**.

In a typical transvascular device, such as a balloon catheter **10**, the proximal region of the device is typically in less tortuous anatomy and the bending stiffness is higher to allow the device to be pushed without bowing or buckling. Accordingly, it is desirable to create a microfabricated structure with stiffness that varies along the length of the device. For instance, the stiffness can decrease and/or increase along the length of the device. The stiffness can also decrease then increase and/or increase then decrease. The stiffness of the structure can be adjusted by increasing the beam **34** and/or annular segment **32** dimensions. These are typically varied at the same time in order to create a structure that has a more uniform distribution of stress. However when the width of the annular segment **32** dimension is increased the pitch of the helix is reduced, so that there are fewer bending regions per length, as shown in FIGS. **13**A and **13**B. To offset this effect, the rotational angle between beam **34** sets (two, three, or more beams) can be varied proportional to annular segment **32** width to maintain a relatively constant helical pitch along the length of the device. Compare FIGS. **13**A and **13**B. It can be seen in FIGS. **13**A to **13**C that as the annular segment **32** width increases the rotational angle can be increased without creating ring structures that will be loaded in bending, tension, or compression. This results in a device with higher bending stiffness and improved pushability and resistance to buckling while still retaining relatively isotropic properties in bending. In other embodiments, annular segment widths and rotational angles can be varied (i.e., increased or decreased).

When the tubular member **26** is used as the center support shaft in a single lumen balloon catheter **10** as shown in FIGS. **1-3**, the plurality of slots **28** allows rapid balloon inflation and deflation. The slots **28** are spaced and sized to create an extremely porous structure that allows rapid inflation and deflation from the lumen **30** of the tubular member **26** into the balloon **14**. The ease of inflation and deflation enable the use of higher contrast medium, which enhances balloon visibility under fluoroscopy. The slot configuration also provides good axial strength (in tension and compression) as well as kinking and ovalization resistance when navigating tortuous vasculature. Further, tracking of the balloon catheter **10** is improved by varying the bending stiffness of the tubular member **26** such that it is softer at its distal end. Moreover, the tubular member **26** is more resistant to bowing and buckling during balloon inflation and deflation.

During inflation of compliant balloons it is possible for compressive forces to be created along the center shaft of the balloon. Traditional single lumen balloon catheters utilize a plastic shaft with holes drilled in it for fluid passage. The shaft must be stiff enough to resist buckling yet soft enough to track smoothly through tortuous vasculature. A simple plastic tube is not easily modified to vary stiffness along its length and is also susceptible to local buckling. The disclosed structure is highly kink resistant and easily varied in stiffness by changing beam heights, cutwidths, cut spacing, wall thickness, etc. Column buckling (Euler buckling), regardless of end constraints, is linearly proportional to bending stiffness and varies inversely with column length squared. Thus by stiffening the proximal portion of a shaft and softening the distal end, it is possible to create a net gain in buckling strength while retaining a soft distal tip, particularly for longer and larger balloon sizes (critical for atraumatic tracking) Alternatively, softening the stiffness profile of the entire shaft for shorter and smaller balloons to create maximum distal flexibility may provide better tracking.

Tubular member **26** and/or other components of balloon catheter **10** may be made from a metal, metal alloy, polymer (some examples of which are disclosed below), a metal-polymer composite, ceramics, combinations thereof, and the like, or any other suitable material. Some examples of suitable metals and metal alloys include stainless steel, such as 304V, 304L, and 316LV stainless steel; mild steel; nickel-titanium alloy such as linear-elastic and/or super-elastic nitinol; other nickel alloys such as nickel-chromium-molybdenum alloys (e.g., UNS: N06625 such as INCONEL® 625, UNS: N06022 such as HASTELLOY® C-22®, UNS: N10276 such as HASTELLOY® C276®, other HASTELLOY® alloys, and the like), nickel-copper alloys (e.g., UNS: N04400 such as MONEL® 400, NICKELVAC® 400, NICORROS® 400, and the like), nickel-cobalt-chromium-molybdenum alloys (e.g., UNS: R30035 such as MP35-N® and the like), nickel-molybdenum alloys (e.g., UNS: N10665 such as HASTELLOY® ALLOY B2®), other nickel-chromium alloys, other nickel-molybdenum alloys, other nickel-cobalt alloys, other nickel-iron alloys, other nickel-copper alloys, other nickel-tungsten or tungsten alloys, and the like; cobalt-chromium alloys; cobalt-chromium-molybdenum alloys (e.g., UNS: R30003 such as ELGILOY®, PHYNOX®, and the like); platinum enriched stainless steel; titanium; combinations thereof; and the like; or any other suitable material.

As alluded to above, within the family of commercially available nickel-titanium or nitinol alloys, is a category designated "linear elastic" or "non-super-elastic" which, although may be similar in chemistry to conventional shape memory and super elastic varieties, may exhibit distinct and useful mechanical properties. Linear elastic and/or non-super-elastic nitinol may be distinguished from super elastic nitinol in that the linear elastic and/or non-super-elastic nitinol does not display a substantial "superelastic plateau" or "flag region" in its stress/strain curve like super elastic nitinol does. Instead, in the linear elastic and/or non-super-elastic nitinol, as recoverable strain increases, the stress continues to increase in a substantially linear, or a somewhat, but not necessarily entirely linear relationship until plastic deformation begins or at least in a relationship that is more linear that the super elastic plateau and/or flag region that may be seen with super elastic nitinol. Thus, for the purposes of this disclosure linear elastic and/or non-super-elastic nitinol may also be termed "substantially" linear elastic and/or non-super-elastic nitinol.

In some cases, linear elastic and/or non-super-elastic nitinol may also be distinguishable from super elastic nitinol in that linear elastic and/or non-super-elastic nitinol may accept up to about 2-5% strain while remaining substantially elastic (e.g., before plastically deforming) whereas super elastic nitinol may accept up to about 8% strain before plastically deforming. Both of these materials can be distinguished from other linear elastic materials such as stainless steel (that can also can be distinguished based on its composition), which may accept only about 0.2-0.44% strain before plastically deforming.

In some embodiments, the linear elastic and/or non-super-elastic nickel-titanium alloy is an alloy that does not show any martensite/austenite phase changes that are detectable by DSC and DMTA analysis over a large temperature range. For example, in some embodiments, there may be no martensite/austenite phase changes detectable by DSC and DMTA analysis in the range of about −60° C. to about 120° C. in the linear elastic and/or non-super-elastic nickel-titanium alloy. The mechanical bending properties of such material may therefore be generally inert to the effect of temperature over this very broad range of temperature. In some embodiments, the mechanical bending properties of the linear elastic and/or non-super-elastic nickel-titanium alloy at ambient or room temperature are substantially the same as the mechanical properties at body temperature, for example, in that they do not display a super-elastic plateau and/or flag region. In other words, across a broad temperature range, the linear elastic and/or non-super-elastic nickel-titanium alloy maintains its linear elastic and/or non-super-elastic characteristics and/or properties.

In some embodiments, the linear elastic and/or non-super-elastic nickel-titanium alloy may be in the range of about 50 to about 60 weight percent nickel, with the remainder being essentially titanium. In some embodiments, the composition is in the range of about 54 to about 57 weight percent nickel. One example of a suitable nickel-titanium alloy is FHP-NT alloy commercially available from Furukawa Techno Material Co. of Kanagawa, Japan. Some examples of nickel titanium alloys are disclosed in U.S. Pat. Nos. 5,238,004 and 6,508,803, which are incorporated herein by reference. Other suitable materials may include ULTANIUM™ (available from Neo-Metrics) and GUM METAL™ (available from Toyota). In some other embodiments, a superelastic alloy, for example a superelastic nitinol can be used to achieve desired properties.

In at least some embodiments, portions or all of tubular member **26** may also be doped with, made of, or otherwise include a radiopaque material. Radiopaque materials are understood to be materials capable of producing a relatively bright image on a fluoroscopy screen or another imaging technique during a medical procedure. This relatively bright image aids the user of balloon catheter **10** in determining its location. Some examples of radiopaque materials can include, but are not limited to, gold, platinum, palladium, tantalum, tungsten alloy, polymer material loaded with a radiopaque filler, and the like. Additionally, other radiopaque marker bands and/or coils may also be incorporated into the design of balloon catheter **10** to achieve the same result.

In some embodiments, a degree of MRI compatibility is imparted into balloon catheter **10**. For example, to enhance compatibility with Magnetic Resonance Imaging (MRI) machines, it may be desirable to make tubular member **26**, or other portions of the balloon catheter **10**, in a manner that would impart a degree of MRI compatibility. For example, tubular member **26**, or portions thereof, may be made of a material that does not substantially distort the image and create substantial artifacts (artifacts are gaps in the image). Certain ferromagnetic materials, for example, may not be suitable because they may create artifacts in an MRI image. Tubular member **26**, or portions thereof, may also be made from a material that the MRI machine can image. Some materials that exhibit these characteristics include, for example, tungsten, cobalt-chromium-molybdenum alloys (e.g., UNS: R30003 such as ELGILOY®, PHYNOX®, and the like), nickel-cobalt-chromium-molybdenum alloys (e.g., UNS: R30035 such as MP35-N® and the like), nitinol, and the like, and others.

The entire balloon catheter **10** can be made of the same material along its length, or in some embodiments, can include portions or sections made of different materials. In some embodiments, the material used to construct balloon catheter **10** is chosen to impart varying flexibility and stiffness characteristics to different portions of balloon catheter **10**. For example, proximal section **18** and distal section **20** of balloon catheter **10** may be formed of different materials, for example materials having different moduli of elasticity, resulting in a difference in flexibility. In some embodiments, the material used to construct proximal section **18** can be relatively stiff for pushability and torqueability, and the material used to construct distal section **20** can be relatively flexible by comparison for better lateral trackability and steerability. For example, proximal section **18** can be formed of polyimide shaft and/or doped polytetrafluoroethylene (PTFE) reinforced with 304v stainless steel wire or ribbon variable pick braiding or variable pitch cross wounding and distal section **20** can be formed with multi-durometer polymeric outer jacket such as PEBAX® over variable pick/pitch reinforced structure.

In embodiments where different portions of balloon catheter **10** are made of different materials, the different portions can be connected using any suitable connecting techniques and/or with a connector. For example, the different portions of balloon catheter **10** can be connected using welding (including laser welding/bonding), soldering, brazing, adhesive, thermal bonding or the like, or combinations thereof. These techniques can be utilized regardless of whether or not a connector is utilized. The connector may include any structure generally suitable for connecting portions of a balloon catheter. One example of a suitable structure includes a structure such as a hypotube or a coiled wire which has an inside diameter sized appropriately to receive and connect to the ends of the proximal portion and the distal portion. Essentially any suitable configuration and/or structure can be utilized for connecting various portions of the balloon catheter **10** including those connectors described in U.S. Pat. Nos. 6,918,882 and 7,071,197 and/or in U.S. Patent Pub. No. 2006-0122537, the entire disclosures of which are herein incorporated by reference.

As shown in FIG. **7**, a polymer jacket **40** is laminated over the tubular member **26**. The polymer jacket **40** may be disposed over portions or all of the tubular member **26** that may define a generally smooth outer surface for balloon catheter **10**. In other embodiments, however, such a jacket **40** or covering may be absent from a portion or all of balloon catheter **10**, such that the tubular member **26** may form the outer surface. The jacket **40** may be made from a polymer or any other suitable material. Some examples of suitable polymers may include low density polyethylene (LDPE), linear low density polyethylene (LLDPE), polytetrafluoroethylene (PTFE), ethylene tetrafluoroethylene (ETFE), fluorinated ethylene propylene (FEP), polyoxymethylene (POM, for example, DELRIN® available from DuPont), polyether block ester, polyurethane (for example, Polyurethane 85A), polypropylene (PP), polyvinylchloride (PVC), polyether-ester (for example, ARNITEL® available from DSM Engineering Plastics), ether or ester based copolymers (for example, butylene/poly(alkylene ether) phthalate and/or other polyester elastomers such as HYTREL® available from DuPont), polyamide (for example, DURETHAN® available from Bayer or CRISTAMID® available from Elf Atochem), elastomeric polyamides, block polyamide/ethers, polyether block amide (PEBA, for example available under the trade name PEBAX®), ethylene vinyl acetate copolymers (EVA), silicones, polyethylene (PE), Marlex high-density polyethylene, Marlex low-density polyethylene, linear low density polyethylene (for example REXELL®), polyester, polybutylene terephthalate (PBT), polyethylene terephthalate (PET), polytrimethylene terephthalate, polyethylene naphthalate (PEN), polyetheretherketone (PEEK), polyimide (PI), polyetherimide (PEI), polyphenylene sulfide (PPS), polyphenylene oxide (PPO), poly paraphenylene terephthalamide (for example, KEVLAR®), polysulfone, nylon, nylon-12 (such as GRILAMID® available from EMS American Grilon), perfluoro(propyl vinyl ether) (PFA), ethylene vinyl alcohol, polyolefin, polystyrene, epoxy, polyvinylidene chloride (PVdC), poly(styrene-b-isobutylene-b-styrene) (for example, SIBS and/or SIBS 50A), polycarbonates, ionomers, biocompatible polymers, other suitable materials, or mixtures, combinations, copolymers thereof, polymer/metal composites, and the like. In some embodiments the jacket **40** can be blended with a liquid crystal polymer (LCP). For example, the mixture can contain up to about 6% LCP.

In some embodiments, the exterior surface of the balloon catheter **10** (including, for example, the exterior surface of the tubular member **26**) may be sandblasted, beadblasted, sodium bicarbonate-blasted, electropolished, etc. In these as well as in some other embodiments, a coating, for example a lubricious, a hydrophilic, a protective, or other type of coating may be applied over portions or all of the jacket **40**, or in embodiments without a jacket over portion of the tubular member, or other portions of device **10**. Alternatively, the jacket **40** may comprise a lubricious, hydrophilic, protective, or other type of coating. Hydrophobic coatings such as fluoropolymers provide a dry lubricity which improves device handling and device exchanges. Lubricious coatings improve steerability and improve lesion crossing capability. Suitable lubricious polymers are well known in the art and may include silicone and the like, hydrophilic polymers such as polyarylene oxides, polyvinylpyrolidones, polyvinylalcohols, hydroxy alkyl cellulosics, algins, saccharides, caprolactones, and the like, and mixtures and combinations thereof. Hydrophilic polymers may be blended among themselves or with formulated amounts of water insoluble compounds (including some polymers) to yield coatings with suitable lubricity, bonding, and solubility. Some other examples of such coatings and materials and methods used to create such coatings can be found in U.S. Pat. Nos. 6,139,510 and 5,772,609, which are incorporated herein by reference.

The jacket **40** may be formed, for example, by coating, extrusion, co-extrusion, interrupted layer co-extrusion (ILC), or fusing several segments end-to-end. The layer may have a uniform stiffness or a gradual reduction in stiffness from the proximal end to the distal end thereof. The gradual reduction in stiffness may be continuous as by ILC or may be stepped as by fusing together separate extruded tubular segments. The jacket **40** may be impregnated with radiopaque filler materials such as barium sulfate, bismuth, or tungsten to facilitate radiographic visualization. Those skilled in the art will recognize that these materials can vary widely without deviating from the scope of the present invention.

The distal portion of the balloon **14** is attached to the distal end of the tubular member **26** and to the distal flexible tip distal of the inflation ports/irrigation channels. The balloon **14** is positioned on the tubular member **26** such that the balloon **14** overlies the portion of the tubular member **26** having slots **28** formed therein. The balloon **14** may be made of a highly compliant material that elastically expands upon pressurization. Because the balloon **14** elastically expands from the deflated state to the inflated state, the balloon **14** has an extremely low profile in the deflated state and may be used without folding the balloon. The balloon may be formed of silicone, urethane polymer, or an extruded thermoplastic elastomers polyisoprene rubber such as a 70A, 65A, 60A, 52A, 45A, 42A, 40A, 32A, 30A, 25A, 15A, 12A, and 5A durometer hydrogenated polyisoprene rubber, which is commercially available under the trade name Chronoprene™ and Mediprene™ from AdvanSource Biomaterials, Inc. and Elasto, respectively. Hydrogenated polyisoprene provides a balloon having superior performance and manufacturing attributes. In particular, hydrogenated polyisoprene may be processed with standard polyolefin processing equipment to obtain balloon tubing having a wall thickness of approximately 0.001 inches to 0.010 inches and a corresponding inside diameter of approximately 0.016 inches to 0.058 inches. Such tubing produces balloons having a nominal inflated outside diameter of approximately 3.0 mm to 7.5 mm. The highly compliant balloon preferably elastically expands at pressures less than 1.0 ATM. The highly compliant balloon may have a pressure compliance of 2.0 mm/ATM or more at pressures less than 2.0 ATM. The highly compliant balloon may have a volumetric compliance of approximately 0.3 mm per 0.01 ml to 0.5 mm per 0.01 ml at pressures less than 2.0 ATM, for balloons having a nominal diameter of approximately 3.5 mm and a length of approximately 10 mm to 30 mm. The ends of the balloon are attached to the tubular member **26** and the flexible distal tip using conventional bonding means such as thermal bonding using a hot jaw, hot air source, or a laser. The tubular member **26**, excluding the balloon **14** and distal flexible tip, can be coated with hydrophilic coatings such as Hydropass, Hydrolene or Bioslide.

As shown in FIG. **4**, marker bands **42** are mounted on the tubular member **26**. FIG. **5** shows the recessed wide annular segment **44** configured to hold the cylindrical marker band **42** in FIG. **4**. Further, the annular segments **32** on either side of the recessed wide annular segment **44** are raised relative to the recessed wide annular segments **44** (not beyond the outer diameter of the tubular member **26**) to retain the marker band **42** therein. The marker band **42** may be made of a full band, slit band, or coil wound of round or ribbon wire made of materials like Platinum/Tungsten, Gold. The marker band **42** may also be made from a low durometer polymer or any other suitable materials impregnated with radiopaque filler materials such as Barium Sulfate, Bismuth or Tungsten to facilitate radiographic visualization. Some examples of suitable polymers may include low density polyethylene (LDPE), linear low density polyethylene (LLDPE), elastomeric polyamides, block polyamide/ethers, polyether block amide (PEBA, for example available under the trade name PEBAX®).

As shown in FIG. **14**, a balloon catheter **10** may be manufactured by first mounting a tubular member **26** in a trimming device (step **68**). Next, a first annular segment **32** of the tubular member **26** is fed distally through the trimming device (step **70**). Then, a first slot **28** is formed into the tubular member **26** proximal of the first annular segment **32**, e.g. by laser cutting (step **72**). Subsequently, a first oblique angle is formed at a first end of the first slot **28** (step **74**).

Next, a second oblique angle, perpendicular to the first oblique angle, is formed at a second end of the first slot **28** (step **76**). Then, the tubular member **26** is rotated 180 degrees about its longitudinal axis (step **78**). Subsequently, a second slot **28** is formed into the tubular member **26** proximal of the first annular segment **32** (step **80**).

Next, a third oblique angle is formed at a first end of the second slot **28** (step **82**). Then, a fourth oblique angle, perpendicular to the first oblique angle, is formed at a second end of the second slot **28** (step **84**). Subsequently, the next annular segment **32** of the tubular member **26** is fed distally through the cutting device (step **86**).

Next, tubular member is rotated a small angle (about eight degrees) about its longitudinal axis (step **88**). Step **72** to step **88** are repeated until a plurality of slots **28** have been cut into the tubular member **26** (step **90**), at which time the tubular member **26** is removed from the trimming device (step **92**). In some embodiments, the tubular member **26** is covered with a polymer jacket **40**.

Finally, when making a balloon catheter **10**, a balloon **14** is attached to the tubular member **26** so that the balloon **14** defines a lumen in communication with at least one slot **28**.

FIG. **15** depicts a balloon catheter **10** having a balloon support shaft **24** with slots **28** formed therein and a balloon **14** overlying the balloon support shaft **24**. The balloon **14** may be made of ChronoPrene™ and the balloon support shaft may be a nitinol tube with slots **28** micro-machined therein. The proximal and distal ends **46**, **48** of the balloon **14** overly proximal and distal sections **50**, **52** of the balloon support shaft **24**, respectively. As a result of the manufacturing process, the proximal and distal sections **50**, **52** of the balloon support shaft **24** are covered by a polymer (e.g., polyethylene) jacket **40**, creating proximal and distal spaces **54**, **56** in the balloon **14**. These spaces **54**, **56** are "dead" in the hydrodynamic sense because they fluids cannot flow through the spaces **54**, **56** without changing direction. Consequently, as the balloon catheter **10** is being flushed, air bubbles collect and/or become trapped in the proximal and distal spaces **54**, **56** as described above. Pressure in the balloon catheter **10** drops in a distal direction along the longitudinal axis of the balloon catheter **10**. Accordingly, most air bubbles migrate to the distal space **56**. The air bubbles may be 1 mm or larger and may lead to complications such as imaging difficulties and air emboli. The balloon catheter **10** also includes marker bands **42** inside of the balloon **14** that are also covered with the polymer jacket **40** and increase the size of the dead spaces **54**, **56**.

FIGS. **16-18** depict a balloon catheter **10** similar to the one depicted in FIG. **15**. In this embodiment, the distal section **52** of the balloon support shaft **24**, which underlies the distal end **48** of the balloon **14** and the distal space **56**, is not covered by a polymer jacket **40**. Accordingly, the slots **28** in the distal section **52** of the balloon support shaft **24** allow communication between the interior **58** of the balloon **14** and the lumen **30** of the balloon support shaft **24**. Any air bubbles that collect and/or become trapped in the distal space **56** may be flushed out of the distal space **56** by fluid flowing from the interior **58** of the balloon **14** and the lumen **30** of the balloon support shaft **24**. From the lumen **30**, the air bubbles can be harmlessly flush out of a distal opening **60** at the distal end of the balloon support shaft **24**. Such fluid may be introduced from an inflation source **22** attached to the proximal end of the balloon catheter **10**, through the slots **28** in a middle section **62** of the balloon support shaft **24**, and into the interior **58** of the balloon **14**.

As shown in FIG. **18**, the slots **28** in the distal section **52** of the balloon support shaft **24** extend completely around the circumference of the balloon support shaft **24**. This design allows collected and/or trapped air bubbles, which may be located anywhere on the circumference of the balloon support shaft **24**, to be flushed from the interior **58** of the balloon **14** via the slots **28** in the distal section **52**. This design also increases the flexibility and trackability of the distal portion **20** of the elongate member **16** of the balloon catheter **10**.

FIG. **19** depicts an alternative embodiment of a balloon catheter **10** similar to the one depicted in FIGS. **16-18**. In this embodiment, the proximal section **50** of the balloon support shaft **24**, which underlies the proximal end **46** of the balloon **14** and the proximal space **54**, is also not covered by the polymer jacket **40**, like the distal section **52** of the balloon support shaft **24**. This design allows air bubbles that collect and/or become trapped in the proximal space **54** to be flushed out of the proximal space **54**, into the lumen **30**, and out of the distal opening **60** of the balloon support shaft **24**, as described above. Air bubbles tend to collect and/or become trapped in the proximal space **54** in larger diameter compliant and super compliant balloons **14**.

FIG. **20** depicts another alternative embodiment wherein flow out of the proximal and distal spaces **54**, **56** is increased by forming slots **28** in the marker bands **42** that are at least partially aligned with the slots **28** in the balloon support shaft **24** underlying the marker bands **42**. The slots **28** in the marker bands **42** allow flow through the bands, thereby increasing the ability to flush air bubbles from the proximal and distal spaces **54**, **56**, as described above. The slots **28** in the marker bands **42** also increase the flexibility and trackability of the distal portion **20** of the elongate member **16** of the balloon catheter **10**. In still another embodiment (not shown), the slotted marker band **42** is replaced with a radiopaque coil having a large pitch wherein openings in the coil are at least partially aligned with the slots **28** in the balloon support shaft **24** underlying the coil.

FIGS. **21** and **22** depict yet another alternative embodiment wherein instead of open slots **28** being formed in the distal section **52** of the balloon support shaft **24**, a vent hole **64** is formed in the distal section **52**, e.g., by laser drilling. The vent hole **64** allows air bubbles that collect and/or become trapped in the distal space **56** to be flushed out of the distal space **56**, into the lumen **30**, and out of the distal opening **60** of the balloon support shaft **24**, as described above.

To prepare a balloon catheter **10**, such as the one depicted in FIGS. **16-18**, for use, the balloon catheter **10** is first flushed. Fluid is introduced into the lumen **30** of the balloon support shaft **24** from an inflation source **22** attached to the proximal end of the balloon catheter **10**. Pressure from the inflation source **22** drives the fluid from the lumen **30**, through the slots in the middle section **62** of the balloon support shaft **24**, and into the balloon **14**. As the fluid travels through the balloon catheter **10**, it drives the air out of the balloon catheter **10**. However, some air may be trapped in the system as air bubbles. These bubbles tend to collect and/or become trapped in the annular space between the inner surface of the balloon **14** and the outer surface of the balloon support shaft **24**, and more particularly in the distal space **56** in the balloon **14**.

The fluid travels through the interior **58** of the balloon **14** and exits through the slots **28** in the distal section **52** of the balloon support shaft **24**, and back into the lumen **30**. As the fluid exits through the slots **28** in the distal section **52**, it carries any trapped air bubbles from the distal space **56** into the balloon support shaft lumen **30**. From the balloon support shaft lumen **30**, the fluid and the air bubbles are flushed out of the distal opening **60** of the balloon support shaft **24**.

After flushing, the balloon **14** is inflated by closing the distal opening **60** and visually inspected for air bubbles. The balloon **14** may be inflated by advancing a guidewire past the distal opening **60** to occlude and seal against an annular tip seal **66** disposed in the lumen **30** of the balloon support shaft **24** distal of the distal section **52**. Occluding and sealing against the annular tip seal **66** allows the balloon **14** to inflate through the slots **28** in the balloon support shaft **24**. The annular tip seal **66** may be made of ChronoPrene™ 70A, 65A, 60A, 52A, 45A, 42A, 40A, 32A, 30A, 25A, 15A, 12A, or 5A durometer. If an unacceptable amount of air bubbles (of a certain size) is identified in the balloon **14** after inflation, the balloon catheter **10** is flushed again until the amount of air bubbles identified in the inflated balloon **14** is acceptable.

What is claimed is:

**1**. A balloon catheter, comprising:

an elongate support member comprising a tubular wall defining first and second openings therein, open proximal and distal ends, and an axial lumen in communication with the first and second openings and the open proximal and distal ends; and

a balloon disposed on the elongate support member, the balloon defining a balloon interior through which the elongate support member extends,

wherein the balloon interior has a proximal end region, a middle region, and a distal end region, with the first opening located in the middle region, and the second opening located in the distal end region, such that the support member lumen is in communication with the balloon interior through each of the first and second openings, and such that a pressurized liquid introduced through the open proximal end of the support member will enter the balloon interior through the first opening, and subsequently exit the balloon interior through the second opening, back into the lumen, and out the open distal end of the support member, and

wherein a radipaque marker is disposed on the elongate support member in the distal end region of the balloon interior, proximal of the second opening.

**2**. The balloon catheter of claim **1**, wherein the second opening is a slot defined by the elongate support member.

**3**. A balloon catheter, comprising:

an elongate support member comprising a tubular wall defining first and second openings therein, open proximal and distal ends, and an axial lumen in communication with the first and second openings and the open proximal and distal ends;

a balloon disposed on the elongate support member, the balloon defining a balloon interior through which the elongate support member extends,

wherein the balloon interior has a proximal end region, a middle region, and a distal end region, with the first opening located in the middle region, and the second opening located in the distal end region, such that the support member lumen is in communication with the balloon interior through each of the first and second openings, and such that a pressurized liquid introduced through the open proximal end of the support member will enter the balloon interior through the first opening, and subsequently exit the balloon interior through the second opening, back into the lumen, and out the open distal end of the support member; and

a radiopaque marker disposed in the balloon interior on the elongate support member between the first opening and the second opening, the radiopaque marker comprising a marker tubular wall defining a marker opening therein, wherein the tubular wall of the elongate support member also defines a third opening therein at least partially underlying the marker opening, such that the support member lumen is in communication with the balloon interior through the third opening and the marker opening.

**4**. The balloon catheter of claim **3**, the radiopaque marker comprising an open pitch coil.

**5**. The balloon catheter of claim **1**, wherein the elongate support member is a metal hypotube, and the first and second openings are micro-machined therein.

**6**. The balloon catheter of claim **1**, wherein the elongate support member is a polymeric tube, and the first and second openings are drilled therein.

**7**. The balloon catheter of claim **1**, wherein the elongate support member further comprises a polymeric sleeve disposed around a portion of the elongate support member, and wherein the portion of the elongate support member in which the second opening is formed is free of the polymeric sleeve.

**8**. The balloon catheter of claim **1**, wherein the elongate support member further comprises an annular seal disposed in the lumen distal of the balloon.

**9**. The balloon catheter of claim **1**, wherein the tubular wall also defines a third opening located in the proximal end region, such that the support member lumen is in communication with the balloon interior through the third opening, and such that a pressurized liquid introduced into the open proximal end of the support member will enter the balloon interior through the first opening, and subsequently exit the balloon interior through the second and third openings, back into the lumen, and out the open distal end of the support member.

**10**. The balloon catheter of claim **9**, wherein the balloon comprises a compliant or super compliant material.

**11**. A balloon catheter, comprising:

an elongate support member comprising a tubular wall defining first, second, and third slot-shaped openings therein, open proximal and distal ends, and an axial lumen in communication with the first, second, and third openings and the open proximal and distal ends; and

a balloon disposed on the elongate support member, the balloon defining a balloon interior surrounding a portion of the elongate support member,

wherein the balloon interior has a proximal end region, a middle region, and a distal end region, with the first opening located in the middle region, the second opening located in the distal end region, and the third opening located in the proximal end region, such that the support member lumen is in communication with the balloon interior through each of the first, second, and third openings, and such that a pressurized liquid introduced through the open proximal end of the support member will enter the balloon interior through the first opening, and subsequently exit the balloon interior through the second and third openings, back into the lumen, and out the open distal end of the support member,

wherein a radiopaque marker is disposed on the elongate support member in the distal end region of the balloon interior, proximal of the second opening.

**12**. The balloon catheter of claim **11**, the radiopaque marker comprising a marker tubular wall defining a marker opening therein, wherein the tubular wall of the elongate support member also defines a fourth opening therein at least partially underlying the marker opening, such that the support member lumen is in communication with the balloon interior through the fourth opening and the marker opening.

**13**. The balloon catheter of claim **12**, the radiopaque marker comprising an open pitch.

**14**. The balloon catheter of claim **11**, wherein the elongate support member further comprises a polymeric sleeve disposed around a portion of the elongate support member, and wherein the portions of the elongate support member in which the second and third openings are formed are free of the polymeric sleeve.

**15**. The balloon catheter of claim **11**, wherein the elongate support member further comprises an annular seal disposed in the lumen distal of the balloon.

**16**. The balloon catheter of claim **11**, wherein the balloon comprises a compliant or super compliant material.

* * * * *